**COLOMBIA**

MANUAL TOEXAMINE FORM AND CONTENT

OF THE INVENTION AND UTILITY MODEL PATENT APPLICATIONS

Version 2

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**INTRODUCTION**

Dear patent examiners:

The governmental actions aimed at strengthening the institutions and at assuring an administration focused on the timely and adequate public service offering to the citizens, constitute an important challenge imposed to each entity in the different sectors of the public service. The Superintendence, as a public entity, cannot disregard these challenges; conversely, it assumes those challenges by accepting the best managerial practices of the systems or regimes it is responsible for, under the rules to which the public function legally appointed thereto has been submitted.

In view of the foregoing, and in compliance with that disposed by Act 872 of 2003 which establishes the Quality Management System and the guidelines that each entity must develop in an integrated, intrinsic, reliable, economic, technical, and particular manner, we have considered useful and necessary to write down guidelines, manuals, rules, instructions, etc. that follow accurately the institutional purposes –in compliance with the standards described in technical standard NTCGP:1000– and evidence the improvement the entity is committed to observe regarding its competencies, including all aspects of Industrial Property.

The Integrated Quality Management System documentation not only constitutes the exercise of a function that has been legally assigned to the Superintendence of Industry and Commerce by virtue of Decree 4886 of 2011 which commands the Superintendence to adopt the necessary regulations, manuals, and instructions for the proper performance of the Entity; also, compliance with the documentation is compulsory for all its officers with the purpose of helping them assure that all their actions conform to the institutional goals, quality, and efficiency in the offering of the missionary services and the satisfaction of the users' needs.

Consequently, this manual materializes the rules established in the abovementioned regulations and under the Andean regime, with the process entity has to carry out to decide upon the patentability of the inventions.

To achieve that, this document compiles technically and in order all the guidelines and criteria that the entity has been applying to perform the examination of the patent applications in Colombia, in compliance with the regulatory framework contained in Decision 486. Therefore, all the officers in charge of solving these issues are

expected to have answers to their inquiries at hand to facilitate decision making with the purpose of achieving better patent application evaluation standards and offer a better service to the users of the Industrial Property system.

However, it is important to stress on the scope of the Manual because its purpose is to improve management and not to complement or replace the current intellectual property regulations contained in Decision 486 of the ACN [Andean Community of Nations]. On the contrary, the Manual is a reference, guidance, and support tool to address and execute the missionary process of managing the Industrial Property system that includes the study of patent applications and the decisions that must be taken therefor.

Thus, if the examiner considers that there exists (at any moment during the application or consultation) any kind of contradiction between the content of this Manual and the supranational regulations that govern the industrial property issues in the country, no other course will exist to solve any doubt but the literal meaning of the latter, because its legal nature prevails upon any other contradictory legal or administrative disposition.

Messrs. Examiners, we want to finish transmitting the message that the Superintendence of Industry and Commerce is an entity that permanently performs continued improvement processes in order to achieve the full satisfaction of all our users. In this line of thought, we expect this examination Manual to be a daily work tool to make your work gentler, more efficient, and opportune, thus contributing to the continued improvement of the service.

PABLO FELIPE ROBLEDO DEL CASTILLO
SUPERINTENDENT OF INDUSTRY AND COMMERCE

JOSÉ LUIS LONDOÑO FERNÁNDEZ
DEPUTY SUPERINTENDENT FOR THE INDUSTRIAL PROPERTY

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# 1. CHAPTER I. FORM EXAMINATION OF THE APPLICATION

## 1.1 Filing of the Application

Applications must be filed in writing along with proof of payment of the corresponding fee without prejudice to the Superintendence electronic service to file the applications.

To file the applications, we recommend using Arial typeface; and the letter size must be 12 points with a 1.5 line spacing.

## 1.2 Receipt and filing of the application

The person in charge of the Information and Documentation Center or the department appointed to receive the applications must take into account that the invention or utility model patent application must contain the minimum information required in order to be assigned a filing date from which the administrative process aimed at obtaining a patent will be carried out. Thus, the assignment of a date grants priority rights over the applications that might be filed at a later time in Colombia and in the countries where the applicants would like to protect their invention.

The person in charge must verify the following requirements:

a) A reference that the granting of a patent is expected: This requirement is fulfilled by filling out the patent application form PI02-F01 established by the Superintendence or an identical one and crossing the corresponding section and the category chose, that is, invention or utility model patent, as the case may be.

b) Applicant’s information to allow the Superintendence to contact that person. As a result, the applicant’s full name and their physical or electronic address might be enough (particularly, the electronic address to communicate faster.)

c) The description of the invention. To comply with this requirement it is unnecessary to determine whether the description is clear enough or sufficient; filing a writing with a description explaining the invention in an intelligible form might suffice.

d) Drawings, if pertinent. They must be understood as those drawings that may explain properly the invention.

e) Proof of payment of the respective fee. The examiner must validate that the amount corresponds to the current rates established in the latest resolution issued by the Superintendent of Industry and Commerce.

In case of a missing requirement, the applicant must be informed about the need to fulfill it. If the applicant insists on filing the

application, the documents will be received as an incomplete petition, and a filing date will be assigned, but it will not be considered the filing date of a patent application.

In such case, the officer in charge writes an official letter informing about the missing requirement and compelling the interested party to complete the documentation within the next two (2) months. If the missing requirement is some kind of information to identify the applicant, the number of the incomplete petition is published in the official communication sent to the applicant by the Office. If the applicant does not complete the application, it will be deemed waived in accordance with that provided by the Administrative Contentious Code, and the file will be closed.

The application's filing date and number are assigned only when the applicant fulfills the minimum requirements; that is, when the application is complete.

Verification of the documents at the filing is merely formal and limits to determining the existence of the elements appointed in articles 33 of Decision 486.

In case the documentation is filed before one of the authorized entities different to the Superintendence of Industry and Commerce, such as the Superintendence of Companies and the Chambers of Commerce in other cities of the country, the minimum requirements must be fulfilled as well in order to be assigned a filing date and consider the existence of an invention or utility model patent application.

Revision of the minimum information is performed at the Documentation and Information Center of the Superintendence, and in various entities nationwide that are authorized to receive the applications, until the applicant is informed that a missing requirement is causing the non-assignment of a filing date; if the applicant insists on the filing, the Documentation and Information Center or the authorized entity must sent the file to the Form Examiner to proceed with the terms referred above.

**PCT [Patent Cooperation Treaty] Applications**

The international filing date is considered as the national filing date if the application that intends to enter the national phase complies with the minimum requirements established in the PCT. The examiner must verify that the international filing date mentioned in the petition is equal to the international filing date mentioned on the first page of the international publication.

The date assigned to the international application by the receiving Office will be taken into account by the SIC to examine patentability.

The examiner must verify that Colombia has been mentioned in the international publication page. For that, the examiner must look up in the World Intellectual Property Organization's (WIPO) page, which is the entity responsible for managing the PCT international system.
Without prejudice to the international filing date, the officer in charge of the filing assigns a filing date to the application; but this date will depend on compliance with articles 33 et seq. of Decision 486, if the national phase is not applicable due to the non-fulfillment of the minimum requirements to enter this phase.

**Execution of the proceeding before 31 months**

The examiner must verify the international filing date or the priority date of the application that is entering the national phase with the purpose of validating compliance with the term to file the application in Colombia. If it was filed before the expiration of the term, the office can start the process to study the application.

**Restoration of rights**

The examiner must bear in mind that as a consequence of the non-fulfillment of the minimum requirements needed to enter the national phase, the application can be declared withdrawn/waived. Nevertheless, the applicant can file a petition to reinstate the right according to that provided by the PCT Regulations and the Superintendence Sole Official Publication.
The examiner must verify that requirements included in rule 49.6 of the norms have been fulfilled. Said reinstatement application can be exercised by filing a petition (before the Superintendence) that contains the reasons why the applicant did not complete the actions provided in articles 22 or 39.1) of the Treaty within the term indicated, along with the supporting documents to credit, for example, that the applicant acted in a timely manner taking all the necessary steps to file the application on time; also, the examiner must verify that the proof of payment of the fee established in the superintendence's fee resolution is attached thereto.
If the form examiners notice that a petition does not comply with the established requirements, or that the applicant does not prove that the non-fulfillment was unintentional, they must issue a requirement compelling the applicant to fulfill the missing requirements or complement them within 2 months as of the notice date.
If the applicant replies and the petition complies with the requirements, the applicant's right will be reinstated by an official letter.

### 1.3 Content of the application

To verify the content of the application, use formats PI02-F13 and PI02-F14 Form examinations, conventional applications – Checkup list and Form examinations, PCT Applications

#### 1.3.1 Petitioning

The examiner must verify that the national patent application form is included in the application; currently, form PI02-F01 is used for national patents or for those claiming priority under the Paris Convention [for the Protection of Industrial Property]; and form PI02-F06 is for PCT applications that enter the national phase and must contain the following:

##### 1.3.1.1 The declaration that the applicant wants to be granted a patent

The form examiner must verify whether the applicants mention the category of the application they want to process according to the protection expected by marking the corresponding box of an invention or utility model patent, as the case may be.

In case the applicant does not mark the respective box, the category of the application will be determined according to the filing fee paid If the fee does not correspond to any of the categories, the examiner will assume that the category of the application is invention patent and will ask the applicant to pay the outstanding amount to complete the fee that corresponds to said category or to clarify the expected right.

Once the application's category is explained, the examiner must verify that the system is reporting the application correctly as per the category of the application that will be studied thereinafter.

**PCT applications**

The examiner must verify that the petitioning is in place; this is a printed format by which applicants declare their interest that the international application enter the national phase (please refer to 1.3.1)

The examiner must verify that applicants have stated the type of protection in the petitioning; that is, if they are applying for protection for an invention or utility model patent. If applicants do not mention the type of protection the application will be processed in accordance with the amount paid.

**Changes in the national phase**

The examiner must verify that there are no changes to the original application at the entrance into the national phase (in the understanding that the original is the international application with its changes)

**1.3.1.2 Applicant**

If the applicant is a natural person, the examiner must verify the name, address, nationality, domicile, identification (ID card, taxpayer identification number, foreign resident identity card, or else, as the case may be), phone number or fax, and the e-mail address of the applicant.

If the applicant is a legal person, the examiner must verify the existence of the information supplied in order to determine accurately who the applicant is and to communicate the decisions of the process and content that the entity will make.

**Applications PCT**

The examiner will verify whether there have been any changes to the application regarding the bibliographic information, such as the change of applicant, and that the respective WIPO form (PCT/IB306/306 Rule 92 bis.1) is in place. Likewise, the examiner must analyze if the information regarding nationality and domicile coincides with that reported in the international phase.

**1.3.1.3 Persons entitled to apply for a patent**

Even though the first right over a patent belongs to the inventor, any other person to whom the inventor has assigned the rights can also apply for the patent; this can be done through actions inter vivos or any other cause, or through legal mandate.

Conforming to article 29 of Act 1450 of 2011 (National Development Plan) the service providing or employment contracts assume that the inventor has assigned the right upon the patent in favor of the hiring party or the employer unless the agreement provides otherwise. Therefore, the examiner must verify in the agreement that the parties (inventor and applicant) are the same, and that there is not a clause that establishes expressly the intention of the inventor to not assign the rights upon the patent.

The titleholders of the patents can be both natural and legal persons. If some people come up with an invention together, the rights upon the patent are common amongst them.

If the applicant is a foreigner, the examiner must verify that the person submits the corresponding document in which the titleholder (assignor) is transferring the rights. This will suffice to credit that the document is legal without needing other forms of acknowledgement/authentication/ notarization.

**1.3.1.4 Representative or attorney/agent**

The patent applications can be processed directly by the interested party or through an attorney/agent –in case of a natural person– or a

legal representative or attorney-at-law –in case of legal persons.
Whenever an attorney/agent acts in the name of a Principal, the examiner must verify that the respective power of attorney is in place.
A special power can be granted through a private document in order to perform one or more industrial property actions identified in that document and does not require personal appearance in compliance with that established in numeral 1.2.1.3 of Resolution 21447 of 2012 by which titles X and XI of the Sole Official Publication are modified.
The powers to withdraw the application or resign to the rights granted must be expressly stated in the power of attorney.
If the attorney/agent resigns or desists, the document expressing such decision must be duly notarized in person by the attorney/agent.
When one person is legal representative or attorney-at-law/attorney/agent of several partnerships or companies at the same time, the examiner must verify the name of the person this attorney/agent is acting on behalf of .
The examiner must keep in mind that it is unnecessary that the applicant, whether national or foreign, prove the existence and/or legal representation of the company he/she is representing, unless there is a reasonable doubt about the veracity of the content of the application. The reasonable doubt is defined in the Sole Official Publication as follows :
The Superintendence of Industry and Commerce is empowered to ask the interested party (during the administrative proceedings related with industrial property) to provide documents to support the application, whenever there may be contradictions or weaknesses/inconsistencies in the information supplied that may affect the efficient development of the proceeding, such as: the identity, existence and legal representation, applicant’s domicile or mailing address, or contradictions related with the attorney/agent appointed for the respective proceeding.
In this case, the applicant or interested party will be required as per that established in article 39 of Decision 486.
The form examiner must verify that the name of the applicant mentioned in the application filed in the country is the same to that of the priority application; otherwise, the applicant will be required to submit a certificate of assignment of rights upon the application (Article 56, Decision 486).

**IMPORTANT NOTE:**

Except in cases of resignation to the rights or withdrawal [of the application], documents to be attached to the application need not be

legalized, acknowledged, or notarized.

**1.3.1.5 Inventor**

The inventor must always be a natural person; and in case there may be several inventors, all of them must be identified and listed in the petitioning. The examiner must verify that the name of the inventor, his/her address, and domicile are stated in the petitioning; the name of inventor can be omitted if he/she opposes to be mentioned as per article 24 of Decision 486.

**PCT applications**

The examiner must verify that the name of the inventor mentioned in the international phase coincides with that in the petitioning of the application that enters the national phase. If there has been a change in the international phase, the examiner must require the applicant to clarify the situation by virtue of the form examination, if there is no coincidence in the number or name of inventors between the international and national applications.

**1.3.1.6 Title of the invention**

The examiner must verify that the petitioning contains the title or name of the invention and that it is the same to the headline of the description.

**PCT applications**

The examiner must verify that the title of the invention entering the national phase coincides with the titles assigned to the application processed in the international phase. The examiner must bear in mind that the applicant modify the title only when the application has already entered the national phase.

**1.3.1.7 International Patent Classification (ICP)**

The form examiner must classify the application temporarily, by turning to the form examiners, if appropriate; or he/she can subject to the international classifications found in the priority applications or those done in the PCT international publication.

During the form examination, the examiner validates the classification assigned by the form examiner, the elements that he/she must consider to classify the application during the form examination; in the case of chemistry applications, the elements are those related to the structure; without prejudice to the foregoing, the examiners can reassign the ICP, when appropriate, keeping in mind the field of application/use.

Should it be necessary to reassign or add a new ICP –in cases of Pure Chemistry Applications– the first consideration is the structure of the compound or, otherwise, the related technical field.

In the pharmaceutical field, the examiner can reassign or add, as the case may be, a new ICP giving priority to the main or largest group, while he/she will take into consideration the classification related with the pharmacotherapy indication.

**1.3.1.8 Proof of payment**

The examiner must verify that a receipt has been attached [to the application] and the amount paid corresponds to the fees established in the respective resolution and that are valid at the moment of the patent application. The resolution can be found in the entity's web page.

**1.3.1.9 Annex**

The examiner must verify that the applicant attached hard copies of the documents marked with an 'x' in the respective boxes of the application form's annexes chapter.

**1.3.1.10 Signature**

The examiner must verify that the applicant or his/her legal representative or attorney/agent has signed the application.

**1.3.1.11 Language**

The examiner must verify that the information included in the petitioning is in Spanish as it is established in article 7 of Decision 486. The other documents conforming the application must also be shown in Spanish. Otherwise, the examiner must verify that the documents are accompanied by the respective translation into Spanish.

**PCT Applications**

If the international application were not filed in Spanish, the applicant must present a translation into Spanish of the international application, as it was originally filed, together with the respective fee paid, no later than thirty-one (31) months as of the priority date

**1.3.1.12 Priority claim**

In case of claiming priority, the examiner must verify the following information:

- Country of origin;
- Filing date; and
- Priority application(s) number(s), in case of claiming multiple priorities.

The information concerning the country of origin and the filing date is essential when filing the application. It is important to validate that the application has been filed within the twelve (12) months following the filing date of the priority application. If multiple priorities are claimed, the term must be counted as of the earlier priority date.

The applicant must file a copy of the priority document no later than sixteen (16) months as of the filing date of the application for which the priority is claimed. The copy must contain the certification of the authority that issued it, together with a certificate of the filing date issued by the same authority and the translation into Spanish, if the original application of which the priority is claimed is in a different language. The term granted by law to attach the declaration and the pertinent documentation cannot be extended; if the foregoing is not achieved within the period granted by law, the priority claim will be dismissed.

The form examiner must verify that the name of the applicant stated in the application filed in the country coincides with the name of applicant in the priority claim; otherwise, the applicant will be required to submit a document of assignment of rights upon the application.

**PCT applications**

The examiner must verify that the applicant has declared, in the petitioning, the priority right claimed and state whether the priority corresponds to one or more applications processed in any of the Country Members of the Paris Convention for the protection of the industrial property or any WTO member that is not part to the Convention.

The priority claimed must contain the following:

- Date of the priority document claimed.
- Number of the priority application.
- Country of origin of the priority application.

If the priority document is available in a digital database/library and has been deposited conforming to the terms provided by the PCT treaty, it is not necessary to file a copy of the document before the SIC at the beginning of the process in the national phase.

The examiner must keep in mind that if the applicant has not filed the priority document of the international application in the period established in rule 17.1a), or under the terms provided by rule 17.1b) or b-bis) of the Regulations, the applicant must file the priority document within 2 months following the date in which the actions that are established in article 22 or 39.1) of the treaty are made, as the case may be, to enter the national phase. However, if the priority document is available in a digital database/library, it will suffice to state the name and URL of the digital library that contains the document, and no requirement for the priority document shall be issued at all.

If by the expiration of the period referred before, the applicant has

not fulfilled the requirement stated above or supplied the necessary information to access to the priority document, the examiner must ignore the priority claim, and the application will continue the process taking the international application date as the filing date .

**Translation of the priority document:**

In accordance to that disposed by rule 51bis. 1e) of the Treaty, the examiner must require the applicant to submit a translation into Spanish of the priority document when validity of the priority claim is relevant to determine whether the invention is patentable or not.

The applicant will have 2 months as of the notification date of the requirement to submit the translation or information demanded as per that established in rule 51 bis.3 of the Regulations.

If by the expiration of the period granted the applicant does not submit the translation or the information required, the examiner must ignore the priority claimed and the application will continue the process .

**1.3.1.12.1 Remedying the omission**

In concordance with that stated and with the discretion to file changes that would not broaden the scope of what was initially applied for, as per article 34 D 486 [abbreviation of Decision 486], the form examiner must consider that the application can be corrected to include omitted matter that was informed while the priority application was processed .

If that is the case, the form examiner will verify the content of the priority application by accessing to WIPO's web page.

If the applicant does not correct the omitted matter that was informed while the priority application was processed, no abandonment of the application will take place and the file will continue to the content evaluation.

Additionally, the examiner must consider that the applicant will not be able to include the omitted matter during the requirement terms established in Article 45 of D 486.

**1.4 Claims**

The claims chapter must consist of one or more claims, taking into consideration that the filing fee covers up to 10 claims; thus, an extra fee must be paid per additional claim exceeding that number. The examiner must verify that the respective proof of payment be attached and correspond to the amount established in the current fees Resolution at the moment the patent application is filed.

**PCT applications**

**Changes made during the international phase by virtue of Chapters I and II of the Treaty:**

The examiner must bear in mind that during the international phase the applicant can make changes to the claims in accordance with that provided by article 19 of the Treaty, once he has received the International Search Report (ISR).

Likewise, once the examiner knows about the result of the international preliminary examination, the applicant can modify the description, claims, and drawings, according to that provided by Article 34 of the Treaty.

The examiner must verify that once the applicant has made the changes to the claims, as a result of the international search report (Chapter I) or during the international preliminary examination (Chapter II), the applicant has attached the changes to the application that is entering the national phase.

If those changes are in a language different to Spanish, the applicant must attach a translation of the claims just as they were modified (Chapter I) in addition to a translation supplied by the applicant. If the changes have been performed by the applicant as a consequence of the international preliminary examination (Chapter II), the translation supplied must also contain the translation of the changes made as per articles 34.2)b) of the Treaty .

When the translation supplied by the applicant does not contain the changes made by virtue of Chapters I or II of the Treaty, the examiner must require the applicant to submit the translation of the changes. If by the expiration of the term granted the applicant has not sent the translation of the changes required, the examiner must ignore said changes and proceed on the basis of the application filed at first .

**1.5 Fees to process the application**

The examiner must verify the payment of the respective fees by checking the proofs of payment for:

- The filing of the application
- The extra words in the publication, if applicable.
- The priority claim, if applicable, taking into account that if there are many priorities, a proof of payment for each priority must be attached thereto.
- For the payment of the priority claims, it is understood that the fee is part of the pertinent documentation used to claim the priority and, therefore, it can be filed together with the application or

separately. The term for an invention and utility model patent application is, in this case, 16 months; but failing to comply with this requirement will cause the withdrawal of the priority (Art. 10 D 486).
- The payment for all the additional claims exceeding 10 claims.
The fee to process an application is determined on a yearly basis and varies according to the patent mode to be obtained; a proof of payment of the corresponding fee must be attached thereto.
There are various payment methods:
First, by making a deposit at the Bank the SIC has an agreement with. The examiner should verify that the file contains the official receipt that corresponds to the deposit voucher submitted to the SIC.
The second, by making an online deposit in the form established by the Superintendence.
Once the processing of the application has started, the Superintendence does not reimburse the fees paid if the application has been withdrawn, the protection requested is denied, or the patent mode –from invention to utility model– has been changed. When the change of mode is from utility model to invention patent, the fee has to be adjusted to the value that corresponds for this last mode.
If the fee for the priority right has not been paid, the right claimed will be lost. Likewise, if the fee for the exceeding number of claims has not been paid, only the first 10 claims included in the application filing fee will be considered.
[The examiner] must verify if the applicant is entitled to discounts at the moment of the filing, according to the current fee Resolution.

**1.6 Copy of contract to access to genetic resources or their byproducts.**
When the products or procedures of the patent application have been obtained or developed from genetic resources or their byproducts originated in any of the Member Countries, the form examiner must verify that:
- The applicants have stated in the petitioning that they obtained or developed the products or procedures, which patent they are applying for, from genetic resources or their by products.
- When the applicants state that they did not use genetic resources or their byproducts, verify they have filled out the negative statement in the petitioning.
- If the applicants inform about the existence of a contract to access to genetic resources or their byproducts filed before the Ministry of the Environment, Housing, and Territorial Development, on a date prior

to the application filing date, the applicants will be able to file a copy of said access contract, its certificate or a registry number, as the case may be.

**1.7 License or authorization to use the traditional knowledge of indigenous, Afro-American, or local communities**

When the products or procedures, which protection has been applied for, have been obtained or developed from said knowledge originated in any of the Member Countries the examiner must verify that:

- The interested party hast informed in the petitioning that the mentioned products or procedures have been developed from traditional knowledge of indigenous, Afro-American, or local communities of the Member Countries.
- There is a license or authorization to use that knowledge or a certificate or a registry number.

**1.8 Deposit certificate of biological material**

The form examiner verifies that the deposit certificate of biological material has been submitted; this certificate must contain the name and address of the institution, the date, and the number of the deposit attributed by said institution. The authorized institutions are those recognized under the Budapest Treaty.

**1.9 Document of assignment by the investor to the applicants or their successors**

When the inventor is a different person to the applicant, the examiner must verify that the document assigning the rights over the patent to the applicants or their successors has been submitted; or, at least, that the application includes an employment or service providing agreement that can lead to think that the rights have been assigned therefor. In cases of inheritance processes, the examiner must also verify the existence of a testament executed or a final judicial decision or a notarial distribution and allocation of the inheritance. If the applicant is a foreigner, the examiner must verify that the corresponding document containing the assignment is attached; nonetheless, in compliance with article 29 of Act 1450 of 2011 (National Development Plan), the service rendering or employment agreements assume that the inventor has assigned the rights upon the patent in favor of the contracting party or employer unless the agreement itself provides expressly otherwise. In fact, the examiner must verify that in the contract the parties (inventor and applicant)

are the same, and there is not a clause that expressly states the will of the inventor to not assign the rights upon the patent.

**1.10 Registration of changes and recordals**

The examiner must keep in mind that the registration of one or more transfers or assignment rights regarding the new creations granted or in process, one single application can be filed provided the assignor and assignee are the same in all the proceedings, and the corresponding file or certificate numbers are clearly mentioned.

Likewise, the examiner must bear in mind that the applicant can request, in a single application, the registration of one or more changes to names, domicile, or address, or any other action that may affect the titleholder of the rights, regarding several applications in process or rights granted, provided the titleholder or applicant is the same, and the corresponding file or certificate numbers are clearly mentioned .

**1.11 Drawings or figures**

The examiner must verify if the descriptive chapter of the application includes drawings. If so, they must include only a reference number, and a brief description or a summary of what the drawings are illustrating must be included in the descriptive chapter; for example: Figure 1 shows a side view of the packaging machine; figure 2 is a partial view of the first functioning stage of the machine shown in figure 1.

If the invention belongs to the field of chemistry, a drawing can be the chemical and structural formulation of one or more compounds.

If the invention is an electric circuit, drawings can be used to indicate the connections between the different elements that constitute the circuit.

Likewise, if the invention corresponds to a process, drawings can show blocks or schematic diagrams that indicate the logical sequence of stages.

Following, we list the possible faults shown in the pages that contain drawings and that the examiner must verify:

- Pages cannot be reproduced directly.
- Pages are crumpled, torn, or folded.
- Pages are not written on one single side.
- Pages are not in the appropriate paper size [official size in Colombia is Legal-like: 8.5x13.2 in]
- Drawings are not placed on a new page

- Pages show corrections or crossing-outs
- They contain superfluous texts
- That drawings are made in black indelible ink, with lines and strokes of uniform thickness.
- The drawings contain sections that are not properly drawn.
- They include elements of a figure that are not proportional among them and are not necessary to improve clarity.
- The drawings contain figures that are not properly placed or clearly separated.
- They contain figures that are not sequentially numbered
- They do not contain some reference symbols mentioned in the description
- They do not limit to the reference symbols mentioned in the description
- Include identical elements designated using different reference symbols

The form examiner checks that the drawings do not contain any texts, except for the necessary brief indications such as water, fume, steam, open, close, section AB, and key words to help understand the drawing. In case those words reduce clarity of the drawings, the applicant may be required to erase them and include these texts in the description, where appropriate.

Words can be used in electrical circuits, or installation, process and/or flow charts/diagrams, but they must be placed in a way they do not cover any of the lines of the drawings.

One same page may contain several drawings, as far as the amount of drawings does not affect the clarity of interpretation per unit or group.

Drawings must be subsequently and correspondingly numbered using Arabic numbers, regardless of the page numbering.

Process stage schemes and diagrams are considered drawings.

If the drawings do not comply with the foregoing, the examiner must require the applicant to file them again with the respective corrections.

If the drawings are submitted after the application filing date, the examiner must determine whether they are necessary to understand the invention and are an essential part to execute it or not.

As the drawings make part of the minimum requirements to grant a filing date as per Art 33 D486, not attaching those drawings leads management to refrain from assigning the filing date. On the contrary, if the examiner considers that the drawings are not necessary to understand

and execute the invention, they can be filed as changes to the application provided the protection that would correspond with the contents of the original application would not be enhanced with the filing of the drawings.

The a posteriori inclusion in the claims of any of the features presented in the drawings filed at first and mentioned in the description does not necessarily imply extending the scope of protection.

If photographs are submitted, they can be accepted only as a complement to the figures but do not replace them. In the cases in which it is impossible to make the presentation with a drawing, it will be possible to file photographs, provided they are in black & white, directly reproducible, and they comply with the applicable requirements for the drawings mentioned above.

Graphic forms not considered drawings:

- Chemical or mathematical formulae.
- Tables

Although the chemical or mathematical formulae and tables are not considered drawings as such, the filing requirements will apply thereto regarding the quality of strokes to allow an acceptable copying/reproduction thereof.

**1.11.1 Main figure**

If the invention considers illustrations/figures and/or chemical formulae, while verifying the technical requirements, the form examiner must, first, check that the final figures have been filed and, second, that they comply with the requirements.

If the applicant has chosen a main figure, its inclusion in the abstract depends on the nature of the invention and the extent to which the abstract per se explains clearly and concisely the objects claimed.

In order to improve clarity and to ease their publication, the examiner must require that any representative chemical formulae of the invention be shown in a separate sheet of paper, as well as any of the figures.

**1.11.2 Approval of the most representative figure of the invention**

The examiner must determine the invention’s most representative figure for the publication; as a general rule, the examiner must approve a single representative figure unless it might be necessary, due to the nature of the invention, to publish more than one to understand the invention better.

## 1.12 Abstracts

**Characteristics and purpose of the abstracts**

The examiner must verify that the abstract explains concisely the art disclosure, the technical field to which the invention belongs, so that it allows a quick understanding of the technical problems; also, the examiner must revise that it corresponds to the description, claims, and drawings filed at first, so that it becomes a necessary and efficient instrument to search the background.

**Content of the abstract**

The standards suggested in the List of WIPO Standards, Recommendations and Guidelines (Part 3 of the WIPO's Handbook on Industrial Property Information and Documentation), which are contained in Standard ST.12/A: Abstracts of patent documents (April 1994); it states that:

"6. THE ABSTRACT SHOULD BE CLEAR AND AS CONCISE AS THE DISCLOSURE PERMITS. It should generally not exceed 250 words and should preferably be in the range of 50 to 150 words. The abstract may contain chemical or mathematical formulae and tables (…)."

However, if the examiner notices an excess of words but they are necessary to give clarity to the abstract, no requirement will be issued unless the abstract is not clear or brief. The abstract may include chemical or mathematical formulae, tables or figures not larger than 12 x 12 cm; they will not count as words within the abstract.

The abstract must not contain declarations related to the advantages associated to the invention.

The structure of the abstract will comprise the following topics:

- Purpose of the invention
- Characteristics of the invention
- Application field

The abstract must address mainly the novelty and contribution of the invention to the state of the art in that field. Therefore, if the invention is a device, procedure, product, or compound, the abstract must focus on the technical description of the change.

**Products or compounds**

If a product is claimed, particularly a compound or composition, and a preparation method or a procedure is also claimed, it must be included in the abstract as well.

Regarding chemical compounds or compositions, the abstract must address the chemical nature of the compound or composition, as well as the application field, and state the chemical formula that better describes the invention.

**Procedures**

Regarding this issue, the abstract must explain the type of reaction, the reagent, and the conditions to carry out the procedure. If the description comprises alternatives or variations in the execution, the abstract must address the preferred variations and identify the other, as long as it can be done briefly; otherwise, the abstract must mention the existence of other variations if they differ substantially from the preferred variation.

The following table determines the content of the abstract (column 2) according to the type of invention:

| If the invention is | The abstract should deal with |
|---|---|
| An article | its identity, use; construction, organization,method of manufacture |
| A chemical compound | its identity (structure if appropriate); method of preparation, properties, uses |
| A mixture | its nature, properties, use; essential ingredients(identify,function); proportion of ingredients, if significant; preparation |
| A machine, apparatus, system | It snature, use; construction, organization; operation |
| A Process or operation | its nature and characterizing features; material and conditions employed; product, if significant; nature of and relationship between the steps, if more than one |

**1.13 Updating of the database by the form examiner**

In this stage the examiner must verify and complement the following information in the system:

- Include the bibliographic data of the patent application in the proceeding system. Once the application is granted a filing date, the officer in charge of examining the form inputs the information contained in the petitioning into the Superintendence database.

**1.14 Opportunity to perform the form examination**

If the application fulfills the minimum requirements, the examiner verifies that it contains the necessary information and documents used

to process and award the patent application. Therefore, it is important that said information and documentation be filed in accordance with that established in articles 26 and 27 of Decision 486.
The form examiner has thirty (30) working days to perform said revision and fifteen (15) working days to proceed similarly in case of utility model patent applications.
It is worth noting that the thirty (30) days mentioned in the Andean regulation are destined to issue the writ of the respective proceeding, that is, to publish the file on the corresponding date or send the requirement official letter for defects in form of the application. Therefore, the examiner must use the thirty (30) days to study the application and not wait until they pass to start the examination.

**1.15 Results of the form examination**

During the form examination or as a result therefrom, any of the following circumstances might occur:
a. That the application complies with all the requirements established by law, in which case it must be sent to the group or officer in charge of publishing the new creation applications; or proceed to publish it directly, if the examiner is also in charge of the publication.
b. That the application was incomplete but the applicant had submitted the information before the Direction issued the requirement official letter. Then, if the information is complete, the examiner performs as in the previous literal.
c. That the application was incomplete both at the beginning and despite additional documents had been submitted. In this case, a requirement official letter is issued using the template established by the New Creations Direction, stating the defects of the application or the missing information.
- The examiner must, then, verify that the applicant has filed a reply during any of the following terms as of the notice date of the requirement official letter: a) Two (2) months for invention patents and one (1) month for utility models; b) two (2) months if an extension has been applied for and the respective fee has been paid.
- Extensions are understood as automatically granted for the respective term as of the expiration date of the first term. Thus, if the term expires the day 30 of any month, the extension term will expire the day 30, two months after, or the next month for utility model patent applications.
- The applicant must pay a fee for the extension application in accordance to that established in the Rates/Fees Resolution, issued

annually by the Superintendence and file the proof of payment along with the extension application.

- If during these terms the applicant does not fulfill the requirements, the application will be considered abandoned, and the examiner must move the file forward to allow the declaration of abandonment.
- If the term to reply to the requirement expires, and the examiner finds that the elements that comprise a patent application comply with the dispositions established by law, the application will pass the form examination and continue the proceeding to the publication stage in the same terms established in literal a) herein.

**1.15.1 Declaration of abandonment**

If the applicant does not reply to the requirement or fails to do it on time, or despite answers to the official comments have been submitted and the examiner finds that the defects still persist, he/she will have to fill out the abandonment template due to a lack of response or non-satisfactory response to the requirement.

**1.15.2 Publication**

The publication will be done in the Industrial Property Gazette.

According to article 40 of Decision 486, the application can be read by third parties, regardless of the application's being published in the eighteenth (18) month or at a stage after that month.

Publication of the patent application has several purposes: First, disclose the invention claimed to allow it become part of the State of the Art, in addition to being a source of information for the general public.

Second goal is to allow interested third parties to oppose to the granting of the patent within the administrative proceeding, by filing reasons or arguments they consider the Superintendence must take into account to deny the privilege claimed.

The term to file the opposition is sixty (60) working days as of the publication date and thirty (30) day for utility models. That term can be extended for as much as sixty (60) additional days for invention patents and thirty (30) additional days for utility models to support the opposition.

The Superintendence will notify the applicants about the oppositions filed and will grant the same terms to file the reasons why they consider their invention is patentable by submitting documents or changes to the application to respond to the claims filed by the opponent.

**1.15.2.1 Term to make the publication**

The examiner must verify, in the petitioning, if the applicant expressly stated his/her will to publish the application before the 18-month term expires –as of the application filing date or the priority claim date (for invention patents); or 12-month period for the utility model applications.

It is important to bear in mind the applicant's intention about the publication of the application, provided the application complies with the formal requirements. If the applicant does not appoint a time prior to the publication, the invention patent application will be published in the month eighteen (18) and the utility models in the month twelve (12).

The form examiner must verify that the format to be published contains the biographical data of the application and check whether the inventor wants to be mentioned in the patent; otherwise, the examiner must delete the applicant's name in the form (Article 24, Decision 486).

Likewise, the examiner must verify that the abstract contains brief information about the purpose of the application, including the essential technical characteristics of the invention and an indication of its use to allow an easy comprehension of the technical character of the topic addressed in the application.

The abstract must not contain declarations related to the advantages or achievements of the invention claimed. If the description comprises execution alternatives or variations, the abstract must address the preferred variations and identify the other to the extent that this identification is brief; otherwise, the abstract must mention the existence of these other variations if they differ substantially from the preferred variation.

In order to give clarity and to facilitate the publication, if one or more representative chemical formulae of the invention are to be published, it is necessary that they are shown separately; this also applies for the figures.

**PCT applications**

PCT applications that have entered the national phase will be published in Spanish once they fulfill the requirements provided by Decision 486, during the same term established for the national applications.

The publication must mention the date the application was filed in the national phase and the filing number. It will also mention the filing number and date of the international application and publication .

**1.16 Opposition**

Once the application is published, whoever has the legitimate interest thereupon may file reasons to rebut or disprove the patentability of the invention (Article 42, Decision 486).

The form examiner must verify whether an opposition has been filed or not; if so, he/she must verify if the term established by law to file this opposition has been fulfilled; namely, sixty (60) days for the invention patents and thirty (30) days for the utility models, as of the publication date.

The Superintendence may grant an extension for the same term upon request of the interested party, in case the opponent required to contend the facts related with the opposition grounds.

The examiner must notify the applicants about the oppositions filed and supply copies of the documents and annexes to allow them to support their argument within the sixty (60) working days after the opposition's filing date. The applicants may then proceed to modify the description and/or claims, if they consider it appropriate, provided these changes do not enhance the purpose filed at first.

The Superintendence will grant just once an additional term of sixty (60) days to respond, upon request of the interested party.

The examiner must verify that the applicant files the corresponding response to the opposition in the term established by law, that is, sixty (60) working days for invention patents or thirty (30) days for utility model as of the publication date. If the applicant requires additional time to respond, the examiner will verify whether the extension was required prior to the expiration of the term that is to be extended.

Extensions must be understood as granted automatically for the respective term; terms will start on the first work day after the expiration of the original term and does not require the administration to pronounce about that circumstance.

## 2 CHAPTER II. CONTENT EXAMINATION

### 2.1 Verifications to be performed prior to the content examination

The examiner must fill out the Content Examination form – Checklist PI02-F15 which corresponds to the following verifications:

#### 2.1.1 That the application has been published

The examiner must verify (with the help of the "Database" of the entity) that the application has been published in the Industrial Property Gazette by checking the consecutive file numbers in order to have a certain date to start counting the term to require the patentability examination.

In case of differences between the application and the publication, the examiner will inform the immediate supervisor to allow him/her to order a new publication.

#### 2.1.2 That a new publication is necessary

A new publication will be necessary when the wrong or omitted information is a substantial factor for third parties to take the decision to file an opposition or change the purpose of the protection without broadening the purpose disclosed at first.

This will be necessary, among other cases, when:

· The abstract published does not correspond to the patent application.

· When the entire abstract has not been published.

· When a procedure is claim but it is replaced by a product.

No new publication will be needed when the error or the omission deals with the applicant's identification data, the international patent classification, or the file number.

The new publication does not modify the six or three-month initial term, as the case may be, to apply for the patentability examination; the 3 and 6 months established by law are counted from the first publication.

#### 2.1.3 That the application is still valid

Verify that there is not an application withdrawal/abandonment/discontinuance letter. If so, the examiner must verify that the person that filed it appeared in person an is empowered to withdraw the application; for example, a attorney/agent may be entitled to withdraw an application if the power of attorney enables him/her to do so. If the withdrawal does not fulfill these requirements, it will not be accepted and the content examination will be carried out.

#### 2.1.4 That priority is verified

Regarding the documents to claim priority, the examiner must verify

that:

O The filing of the application studied that claims priority has been done within the 12-month term as of the priority application date (Art9 D 486)

O The document submitted corresponds to the document referred in the application.

O The priority application's date, country, and number is mentioned.

O The priority application is recorded in the different international patent databases available through electronic means, in case a hard copy has not been submitted.

O Contains proof of payment of the priority fees.

O The technical matter of the application under study corresponds to the matter of the priority application.

O The first application of which the priority right is claimed contains the same technical purpose of the application under study; it is unnecessary that the invention be disclosed identically. However, if one or more of its essential technical characteristics have been generally disclosed in the priority application, and the examiner cannot derive the invention claimed, then he/she will not be able to accept the priority claim.

O The application upon which the priority is claimed is the first application that describes the invention.

**2.1.4.1 Partial priority**

A partial priority consists of the coincidence between one parts of the matter contained in the priority application and the application filed before SIC. Therefore, new matter cannot be included in the application under study. In such case, the priority right is accepted only for the matter that had been disclosed.

To support the search related with the matter not disclosed in the priority application, the state of the art will be determined based on the filing date of the national application under study.

**2.1.4.2 Multiple priorities**

The examiner must verify if the application claims multiple priorities and cannot refrain from considering them to support the search, even though their origin will be different countries or the application under study contains elements that were not included in the priority applications. Regarding these elements, the filing date of the national application under study will be considered to support the search.

O In the case of the search of the elements included in the national application under study and the priority application the filing date

of the earliest priority application will be taken into account.

**2.1.5 That the existence of a patentability examination payment receipt is verified**

The applicant can file a patentability examination petition in writing and attach the proof of payment of the respective fee. Filing the payment receipt without the formal express examination petition must not be understood as if the applicant did not request the examination. In fact, the content examiner must verify only that the applicant paid the corresponding fee within the term established (art 44 D 486).

**2.1.6 Verify the file's most recent events and actions in the "Database" of the Superintendence**

As long as the proceeding is provided physically and not electronically, the examiner must verify, in the database of the Superintendence, if it reports documents that have not been physically attached to the file; in that case, the examiner must require the respective document.

**2.1.7 Conversion of applications**

The examiner must verify that the matter object of protection permit the conversion –required by the applicant or proposed by the examiner– from invention patent to utility model. For this effect, the examiner must make sure that the matter does not address procedures, processes, methods, substances, or compositions and that its patentability is not void.

When the examiner suggests a change of mode, the applicant can accept or reject the suggestion; in case of not accepting it, the proceeding will continue in the original mode.

Regarding the fees, the examiner must verify that the applicant has paid the balance of the filing fee resulting from converting a utility model patent into an invention patent. In case an invention patent is converted into a utility model patent, no fees will be charged as per numeral 1.1.7., Chapter I, Title X of the Sole Official Letter.

**2.1.8 Divisionals**

Like in the case of the changes, the examiner must verify if divisionals were filed. If so, he/she must make sure that none of them imply an extension to the protection that corresponds to the disclosure contained in the parent application .

Likewise, in case of having claimed multiple or partial applications, the examiner must verify that the applicant has mentioned the priority dates that correspond to the matters that should be covered by each partial application.

If these partial applications imply an extension to the matter contained in the parent application and, thus, cannot be accepted for

examination, the examiner must clearly state which the elements that extend the matter are.

The examiner must analyze the partial applications together with the parent application to identify whether after the division the overlapped matter remains. If the partial applications are not properly filed because matter is being claimed in more than one (overlapped matter) all of the them will be accepted for examination; however, during the examination, each partial application will require the correction of the error; that is, said matter must be deleted from one of the applications and left in the other. This means that the study of each partial application must be performed simultaneously.

- SIC can suggest partial applications in the first requirement established by Art. 45 D 486. In this case, if the applicant does not divide the application but files an opinion in favor of the unity of the invention, but the SIC still defends its opinion, one chance will be given to solve the lack of unity of the invention.
- If the second requirement is not fulfilled, the examiner will proceed to decide upon the patent application.
- The applicant will be allowed to divide a partial application again, provided the matter filed in the original partial application is not extended. The original application matter that is not included in any of the partial applications filed as a result of the first division will be deemed withdrawn.
- The applicant may divide the application and file a modality conversion petition.

Also, the examiner must collaborate in the documentary management of the partial applications and of the parent application as follows:

- Verify the presentation of the "Conversion, division, and combination of applications Form" (PI02-F05) in each partial application.
- If necessary, the examiner must reorder chronologically the different actions of the parent application and of each partial applications.
- Verify that each partial application contains the following documents: the petitioning of the parent application and that the filing date, description, claims related to the part, drawings, abstract, powers of attorney, proof of payment of the fee and, if applicable, copy of the access contract, copy of the license or authorization to use the traditional knowledge, certificate of deposit of biological materials, copy of the document stating the assignment of rights upon the patent by the inventor to the applicants or their

successors. It is worth noting that these can be simple copies of the documents filed with the parent application.
- The examiner must validate that the partial applications cite the respective priorities; it is unnecessary to file the priority application again.
- Number all the folios consecutively including the action that the examiner make upon the file.
- The examiner must verify that the applicant has paid the filing fee that corresponds to each partial applications and [include] the necessary documents for the applications (Art. 26 and 36 D 486.)

**2.1.9 Combination of patent applications**

The examiner must verify that the combination does not imply an extension to the protection and that the two applications combination have unity of invention. The priority (or filing) date of the application resulting from the combination will be that of the earliest application.
Finally, the examiner must verify that the fee established for the combination has been paid.

**2.1.10 Analysis of the oppositions**

The examiner must verify that the opposition was filed within the 60-day term as of the filing date or during the time extension, if the opponent required said extension on time and paid the respective fee. The examiner must also bear in mind that if the opponent applied for an extension, it is not necessary for him/her to file the arguments and documents that support the opposition within the initial term. Conversely, he/she will be able to do it within the extension term established for said purpose.
Also, the examiner must verify that the applicant responded to the opposition and required a time extension to respond to it. Similarly to the opposition, the applicant can respond to the opposition during the extension term.
It is important to remember that not responding to the opposition is not a sign against patentability.
Once the examiner has all the documentation at hand, he/she must carry on with the patentability examination with all the pertinent documents in the file, including the opposition and the respective answer.
The patentability examination referred to in article 45 must not state whether the oppositions are justified/well-founded or not. The documents and arguments that the opponent attaches must be considered by the examiner to establish compliance with the patentability requirements of the application. Therefore, declaring the oppositions

well-founded or not must be done in the resolution that grants or denies the application.

In this way, it is possible that the patent be denied due to or based on judgment elements or documents different to those submitted by the opponent, in which case the opposition will be declared unjustified/unfounded in the resolution.

It is also possible to grant the patent, in which case the opposition will be declared unfounded.

Study the documents attached and pronounce about them in the patentability examination of the application.

**2.1.11 Classify the application or reclassify if necessary**

Verify that it conforms to the guidelines of the International Patent Classification (IPC) as per the technical field to which the application under study belongs. This topic is developed in chapter V of this manual.

**2.2 Modifications**

The first part of the study must be focused on warning about the existence or not of modifications to the application in order to know what claims or description chapters are to be considered for the study and the decision.

The examiner must take into account that the limit for the modifications is the prohibition to use them to extend the protection that would correspond to the disclosure contained in the first application. If the modifications go beyond that limit, they cannot be accepted and the patentability examination must fall on the previous claim and/or descriptive chapter.

When the modifications are filed upon request of the applicant, the examiner must verify the proof of payment of the official established fee. On the contrary, it is not necessary to check whether the modifications are filed in response to the request of SIC or not.

When the claims originally filed are not supported in the description because they mention characteristics that are not described, the examiner can suggest their incorporation to the description as such to give support. This change does not imply an extension, provided the matter was included in the first claims and they were filed together with the description (Art. 26 D486).

In case the characteristics that are addressed in the description assume essential elements of the solution to the technical problem but are not included in the claims, the examiner must explain that the claims do not define the matter that is intended to be protected (Art.

30 D 486) and require the inclusion of said essential characteristics in the claims without implying an extension to the matter.
The description can be modified to correct obvious mistakes such as grammar, spelling, and writing mistakes, and typos.
When the description mentions the general elements that conform the compositions such as excipients and active ingredients, in addition to the treatment methods, although the elements may not describe a specific composition, the examiner will, then, accept the modification of the claim chapter from treatment to composition.
For example:
The description mentions: benzo-1-triazol compounds substituted from formula I, pharmaceutical compositions, and processes to prepare it.
Claim 1 refers to: "A method to treat an illness condition interceded by chemokines and that comprises the administration of an efficient quantity of the formula I compound to said mammal."
Claim modified:
"Pharmaceutical compositions that contain a formula I compound and excipients pharmaceutically acceptable."
In this case, the examiner must accept the modified claim because the description mentioned the pharmaceutical compositions that contain the formula I compound.
The modifications allowed in the drawings are: deletion of unnecessary words and changes to reference signs to make them more consistent with the description and to enhance clarity of the drawing's structure.
The untimely filing of a drawing is not an extension to the protection. The Protection is given due to the claims and the drawings help their interpretation.
The abstract can be modified to explain clearly the technical problem and solution, and to exclude commercial or fantasy names or words.
Unaccepted modifications
- Add examples or new effects into the description.
- Add technical characteristics that had not been mentioned at first in the claims or the description.
If the description refers only to a treatment method and does not mention compositions or kits, the examiner must not accept the modification to the claims from treatment method to compound, composition or kit because it is considered an extension of matter.
Now then, if the description refers to a treatment method in which a patient is administered a capsule of the drug "X" and shots of a drug "Y" sequentially or simultaneously, the examiner will not accept the change to the claims of a treatment method to one pharmaceutical

composition that comprises drugs “X” and “Y” and excipients pharmaceutically acceptable, because the description did not state that the drugs were in a single pharmaceutical form but in two separate pharmaceutical forms to be administered to a patient.
If the description and claim chapter filed at first refer only to a treatment method and do not mention compositions or kits that contain the active ingredients, and the modified claim chapter mentions a combination that involves the drugs administered in the treatment method, the examiner will not accept these new claims due to the fact that the combination is still a treatment method.
In such cases, the examiner must tell the applicant the reasons why the modification are not accepted and encourage him/her to make modifications/changes that would not broaden the initial purpose.
The filing of comparative trials or tests to demonstrate the presence of a technical effect or advantage of the invention in respect to the state of the art. Therefore, they must be considered by the examiner to evaluate the patentability of the invention claimed.

### 2.3 Exclusions to patentability

#### 2.3.1 Discoveries

The examiner must consider this:
A discovery is the finding of existing matter that was ignored. It is not considered an invention because it is not the product of the human innovative activity.
A discovery can lead to an invention if it is modified, with the intervention of humans, to give a new technical effect.
Thus, the discoverer just isolates, purifies, and identifies an existing matter, but the inventor modifies also the matter known with the purpose of solving a technical problem.
If a new property of the article or known matter is found, it is a discovery; therefore, it is not patentable; however, if the inventor uses said property in a product, this is an invention that can be patented. For instance, the discovery of a known matter that can resist mechanical shocks is not patentable, but a railroad tie made of this material could be patented.
Finding a substance in nature is a discovery and, thus, not patentable; however, if a substance found in nature has to be isolated in its environment and processed to obtain it, said process could be patented.
On the other hand, if a substance has been isolated from nature and characterizes for its structure or parameters, and its existence has not been recognized yet, it is not considered patentable because said

substance has not been modified, at all, just isolated and characterized.

For example, a substance produced by a microorganism and that has been discovered is not patentable.

Other examples:

Diamond, well known as a precious gemstone, is the hardest mineral and has the property to scratch other materials. Per se, it cannot be patented; but a device using it can. That is the case of the diamond knife used in surgery, which was a revolutionary invention in medicine.

The identification of a plant extract or the gum of a tree bark or the identification of new chemical compounds in that extract or resin, even though it could be isolated or separated from its natural environment, are not considered inventions but discoveries.

### 2.3.2 Scientific theories

As the scientific theories are purely abstract principles where no technical contribution exists, the examiner cannot consider them patentable. For example, the physical theory of semi-conductivity cannot be characterized in technical terms, so that it is not considered an invention and, thus, it is not patentable. However, new semi-conducting articles and the process to manufacture them can be considered inventions and patentable. Likewise, a mathematical formula per se to obtain a temperature is not considered an invention; however, if within a process to obtain a product said formula is used to obtain the temperature needed to carry out said process, this must be considered as different to a mathematic method.

### 2.3.3 The whole or part of living things, natural biological processes, and existing biological material in nature

The examiner must take into account that all living matter or part of any living thing and the substances existing in nature are not inventions. Hence, the simple isolation of biologic material does not make it an invention.

A protein that has been isolated and, moreover, characterized by means of its amino acid sequence, secondary or tertiary structure, molecular weight, polarity, pH, etc. is not an invention because it is the protein as it can be found in nature. In this case, only the characteristics of the protein were identified, but no changes to the protein were made to obtain a different product to the crude or wild protein.

Examples of non-patentable biologic material: GGG transmembrane protein characterized because it is found in the Ebola virus and because it joins to the anti-GGG antibody.

In turn, new pharmaceutical and food products that are obtained from matter found in nature are not excluded from patentability because the material –as it is found in its natural condition– is not claimed.

**2.3.4 Genome or germplasm**

The examiner must take into account that the genome or germplasm of any natural living think, including the human being, is not patentable. Also, the mutation or genetic modification procedures, or other techniques that may be contrary to people's dignity of public order cannot be patented; namely, people cloning, manipulation of human embryos, or creation of human beings in laboratories.

**2.3.5 Literary and artistic works or any other work protected by copyright.**

This type of works are protected by Copyright from their creation. It is unnecessary to register them to obtain the respective protection.

**2.3.6 Plans, rules, and methods to perform intellectual activities, games, or economic-commercial activities.**

The examiner must take into account that they are abstract intellectual creations because they do not use technical means or apply laws of nature, do not solve technical problems, do not produce technical effects, or are not a technical solution. For example, the following are not patentable: methods and systems to manage organizations, economic-commercial activities, traffic rules, methods to edit dictionaries, methods to search information, sales management and promotion procedures, methods to learn a language, games rules and methods, etc.

**2.3.7 Computer programs and the software per se**

The examiner must take into consideration that the computer programs or software are the instructions required by a machine to obtain a result.

In principle, they are not considered inventions because they do not have a technical character as it occurs with the literary works. However, if the application does not refer to a computer program per se, the examiner must perform the patentability examination as per the novelty, inventive step, and industrial applicability requirements and under the provisions of the present manual.

**2.3.8 Ways to show information**

The examiner must consider that any representation of information characterized only for the content of the information is not patentable. This applies if the claim is focused on the presentation of the information per se (for example, using acoustic signals, verbal sounds, visual presentations); on the information recorded by any means (for

example, a book characterized for its content); a recording tape characterized for the recorded music piece; a traffic signal characterized for the warning message; a compact disc characterized for the data or software burned; or a process or device to show information (e.g. a recorder characterized only for the information recorded; or a computer characterized for the data stored.)

**2.4 Patentability exceptions**

The examiner must remember that the following inventions are not patentable:

**2.4.1 Inventions which commercial exploitation must be prevented to protect health or life of people or animals, or to preserve vegetables or the environment.**

The examiner must consider, for example, the following biotechnological procedures:

- Procedures to clone human beings: This procedure consists of creating a human being with the same nuclear genetic information of another human being, either dead or alive.
- Procedures to modify the genetic identity of the human beings' germ line. For example, Germ-line gene therapy in which the therapy not only affects individuals but their progeny because it alters or modifies their gene pool.
- Use of human embryos for industrial or commercial purposes.
- Processes to modify the genetic identity of animal that may cause suffering to them without offering a substantial medical benefit to humans or the animal.
- The human body, in the various formation and development stages and the simple discovery of one of its elements including the total or partial sequence of a gene are not patentable inventions; those formation and development stages include germ cells.
- Procedures to produce chimeras from germ cells or totipotential cells of human beings or animals.

**2.4.2 Inventions which commercial exploitation must be prevented to protect public order or morality**

The examiner must bear in mind that the inventions contrary to public order or morality are not patentable; for example, those promoting uproars, disorder, or arbitrariness; those promoting crime; propaganda supporting racial, religious, or other type of discrimination; and obscene or coarse matter.

**2.4.3 Plants, animals, and procedures that are essentially biological for their production that are biological or microbiological procedures**

The examiner must remember that the plants varieties and species as well as the animal breeds are not patentable. However, the non-biological or microbiological procedure to obtain it might be patentable in a way that the plant or animal would be protected by the patent but the variety of the vegetable or animal species would not. The biologic material, although it might be transformed, is not patentable.

Plant species and varieties, and animal breeds are not patentable. For example, transgenic plants and animals. Modified plants are protected in Colombia by breeder's rights granted by the Instituto Colombiano Agropecuario – ICA [in English, Colombian Livestock and Agriculture Institute].

For example, a not patentable claim is a "cotton plant that resists glyphosate where the genome of the mentioned cotton plant includes one or more selected DNA molecules of a group consisting of SEQ ID N°1, SEQ ID N°2, SEQ ID N°3, and SEQ ID N°4.

In turn, the essentially biologic procedures that are part of a biologic cycle are those processes that are perform in nature without needing the human intervention.

Therefore, the processes that participate in the reproduction of a plant are not considered patentable, although the plant could be transgenic, because the crossbreeding, fertilization, and regeneration process of this plant is still a biological process equivalent to that which occurs in nature, and the transgenic character of the plant does not modify this process.

The following is an example of an essentially biological process that is not considered patentable:

"A method to produce a cotton plant that resists the use of herbicide and comprises:

a) Crossbreed a first cotton parent plant that resists herbicides and comprises the SEQ ID N°1 and SEQ N°2 and a second cotton parent plant that is intolerant to the herbicide to produce plants of the first progeny; and

b) Select a plant of the first progeny that is tolerant to the herbicide; and

c) Self-fertilize the referred plant of the first progeny to produce a plant of second progeny; and

d) Select a plant of the second progeny that is tolerant to the herbicide."

**2.4.4 Therapeutic, surgical, or diagnostic methods**

The examiner must take into account that the therapeutic, surgical,

and diagnostic methods for humans and animals are generally not considered inventions susceptible of industrial applicability.
Therapeutic methods that imply healing of diseases or body dysfunctions are not patentable. Moreover, prophylactic or preventive treatments such as the immunization against diseases are not patentable at all.
A treatment method that consists of the application of a prosthesis to the body is not patentable. However, the prosthesis and the procedure performed outside the human body to make the prosthesis are patentable.
The method to eliminate parasites from the human or animal body is not patentable; for example, the elimination of the worm Taenia solium and the vector ectoparasite of the mange called Sarcoptes Scabiei.
Some treatment methods for animals used in agriculture are not considered treatment methods. For instance, the hormone treatment of livestock such as sheep, pigs, cows, etc. can be patentable because the goal of the treatment is exclusively to increase fertility of females, weight of animals, or an increase in the production of milk.
Contraception methods do not have an industrial applicability because they are used in the intimate parts of women.
In vivo diagnosis methods applied to humans or animals are not patentable; however, in vitro diagnosis methods, even when they require a biologic sample, are eligible for a patentability examination.

**2.5 Uses**

The examiner must consider that the claims which preamble mentions the use of a product or procedure are not patentable.
Also, he/she must consider that, according to the current legislations, the claims that mention an already-patented product or procedure cannot be patented again for the simple fact of attributing a different use to that originally comprised by the first patent.
The examiner must issue the respective requirement informing the applicant that the uses are not patentable under Art. 14 D 486; in case of a second use, issue the requirement under Art.21 D 486 and demonstrate that the product or procedure is comprised by the state of the art and, therefore, a novelty examination must be performed (Art. 16 D 486).
Definition due to a reference to a use:
The examiner must take into account that if a claim defines a product by referring to a use, this claim will be considered a use and, thus

not be patentable, as per Art, 14 D 486.
For example, a claim for a "transistor to be used in an amplifying circuit" is equivalent to a claim of use of the transistor; as a result, the examiner must issue a requirement informing the applicant that the uses are not patentable as per the cited article.
Other example: a claim for the form "substance X to be used as insecticide" must be considered as a claim of use; consequently, it will not be patentable either.

**2.6 Claims**

The examiner must take into consideration that the claims are clauses that outline the object for which the protection is requested. They mention the essential technical characteristics of the object claimed. When the examiners read the claims, they must understand what the object seeking protection is to determine what the essential technical characteristics that define it are because they will be the basis to compare it with the state of the art and determine whether those characteristics are the solution to the technical problem.
The examiners must know that the claims should be clear and brief, and be entirely supported by the description. Likewise, claims can be independent or not: a claim is independent when it defines the matter to be protected without referring to another prior claim; and it is dependent when it defines the matter to be protected making reference to a prior claim. A claim that refers to two or more prior claims will be considered a multiple dependent claim.
The examiner must verify that the claims are shown numbered consecutively.

**2.6.1 Content of the claims**

The claims must contain all the essential technical characteristics of the invention that define it and make it (or should make it) different from the state of the art and, thus, are the solution to the technical problem they are trying to solve.
For the purpose of the examination, the terms related to non-technical aspects such as the results achieved, e.g. commercial advantages, are not considered technical characteristics of the invention because they are not essential characteristics and reduce clarity of the claim. Therefore, the examiner must require the applicant to remove the results expected from the preamble and the characteristic part of the claims.

**2.6.2 Form of the claims**

The examiner must take into account that, although D 486 does not

define the form in which the claims must be shown, this can be done according to the structure "Preamble- grammar connection – characteristic part."

The preamble states what the object of the invention is which normally coincides with the title of the invention (device, process, composition, etc.) and the technical characteristics known in the state of the art.

The grammar connection can be something like "characterized by", "which comprises", or "which consists of".

And the characteristic part states the new technical characteristics that are intended to be protected. As the preamble mentions the technical characteristics known in the state of the art, a typical correction of the objections arising after the search report of the examination consists of identifying in the preamble the characteristic part that the examination describe as known.

**2.6.3 Category of the claims**

**2.6.3.1 Product**

The product claims are refer to physical entities such as object, substance, composition, article, device, machine, system, etc.

**2.6.3.2 Procedure**

The procedure claims refer to the activities ordered by a series of steps in a specific way. For example, a synthesis process, a method to manufacture a device, etc.

**2.6.4 Types of claims**

**2.6.4.1 Independent claims**

An independent claim contains all the essential characteristics of the invention and is self-sufficient. The application may contain more than one independent claim, either of product or procedure, although it is usually clearer if there is only one independent product claim and one independent procedure claim.

Even though the independent claim must specify all the essential characteristics that are necessary to define the invention, it is not necessary to mention the characteristics that are implicit.

For example:

If the claim refers to a "bicycle", it is not necessary to mention the existence of wheels.

If the claim refers to a "composition characterized because it contains X" (being X a new and inventive active principle), it is not necessary to mention the excipients.

If the independent claim is too general and does not mention the essential characteristics because they are described in a dependent

claim, an objection must be informed to the applicant.

**2.6.4.2 Dependent claims**

The examiner must take into consideration that the dependence is due to the fact that all the essential characteristics of the independent claim are present in the dependent claim.

The essential characteristics are the group of elements that solve the technical problem.

Consequently, a dependent claim contains all the characteristics of the claim it depends from, and i) refers to this; and ii) adds one or more characteristics that limit the object to be protected.

The dependent claim can refer to one or more independent or dependent claims or two claims of both types simultaneously, provided the dependence is clear and there are no contradictions.

The dependent claims can refer to particular characteristics of any element of the independent claim regardless it is included in the preamble or in the characterizing part of said independent claim.

A dependent claim is patentable if the independent claim from which it derives is patentable; therefore, in this case, no search is necessary for the dependent claim.

When the examination has demonstrated that the independent claim, which is too general, is not new, but one of the dependent claims mentions the essential characteristic of the invention, the examiner must suggest the applicant to include this essential characteristic in the independent claim and include the other characteristics that are not new in the preamble of said independent claim.

**2.6.4.3 False dependencies**

The relation between the claims is not always a dependency. If a claim refers to another one but does not depend therefrom, the relation is considered a "false dependency".

For example:

A claim of a category refers to other claim of a different category but does not depend on it:

- Claim 1. A product…
- Claim 2. A process to manufacture the product of claim 1.
- Claim 3. A device to perform the process of claim 2.

A claim refers to the other in the same category but does not include all the characteristics of the claim to which it refers:

- Claim 1. A system that comprises a device…;
- Claim 5. A device as per claim 1.

Claim 5, which refers to claim 1 and correspond to the same category, is independent because does not contain all the characteristics of

claim 1.

**2.6.5 Interpretation of the claims**

**2.6.5.1 Terms used**

The meaning and scope of the words in the claims must be the normally used in the technical area of the application and be clear for a Person skilled in the art by just 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, if possible.

Consequently, the examiner must read each claim giving the words the meaning and scope that they normally have in the state of the art unless the description gives them a special meaning. However, if said special meaning applies, the examiner should require the claim to be modified to improve clarity of the meaning.

**2.6.5.2 Open and close type claims**

When the examiner evaluates the novelty or inventive step, he/she must keep in mind the type of transition expression (e.g. "consisting of", "which comprises", "characterized by" or "consisting specially of") used in the claims. The foregoing, given that the object for the search depends on the type of expression used.

- When a claim comprises a close-type transition expression, the examiner will interpret that the products or procedures only comprise elements exposed in the claim. Thus, if a claim refers to a "product consisting solely of A, B, and C", the examiner must interpret that the product comprises only the elements A, B, and C; hence, a product in the state of the art that has A, B, C, and D or any other element does not annul the novelty and, therefore, the examiner would consider it new.
- When a claim comprises an open-type transition expression, the examiner will interpret that the products or procedures include also elements not mentioned in the claim. Thus, if a claim refers to a "product comprising A, B, and C", the examiner will interpret that the product comprises elements A, B, and C, and any other element not mentioned in the claim; hence, a product in the state of the art that has A, B, C, and D or any other element annuls the novelty and, therefore, the examiner will not consider it new.
- For the purpose of the search and examination, the examiner will bear in mind that the expression "consisting specially of" will be interpreted as an open-type expression (as with "comprising", as well), unless the description or claims contain a precise statement that those characteristics are essential.

#### 2.6.5.3 Inaccurate or relative terms

The examiner must issue an objection when the claims include inaccurate terms similar to "approximately", "around", "optionally" because in that case, the scope and protection level of the claim is no longer precise and does not allow a comparison with the state of the art. Non-essential characteristics are permitted provided they are duly justified and allow the examiner to distinguish the state of the art, without leading to ambiguity.

For the same reason, no relative terms such as "greater", "thin", strong" are admitted since they do not convey a precise meaning. Under no circumstance, these terms can be used to distinguish the invention from the state of the art. In these cases, the examiner will need that these expressions be replaced with accurate terms or concrete value ranges.

#### 2.6.5.4 Essential characteristics

The claims must contain all the essential technical characteristics of the invention. Therefore, the examiner must extract them to study how they compare with the state of the art.

Thus, the essential technical characteristics define the invention and make it (or should make it) different from the state of the art and, hence, are the solution to the technical problem that the invention intends to solve.

If an independent claim contains all the essential technical characteristics of the invention, the examiner must not require the applicant to mention other structural characteristics as well.

- Structural technical characteristics:

The characteristics that define the invention are the structural characteristics. For example, the elements that conform a machine, the shape of a part, the chemical structure, etc.

In chemistry and pharmaceutics, the elements that conform the inventions are:

| Compositions | Compounds | Polymorphic | Markush Formulae | Combinations |
|---|---|---|---|---|
| Active compounds | Structural formula and definition of the substituents | X-Ray Diffraction Pattern in dust (minimum 20 peaks) | Structural formula and definition of the substituents | Active Compounds |

| | | | | |
|---|---|---|---|---|
| Excipients | Or IUPAC nomenclature | | | Excipients |
| Proportions | | | | Proportions |
| Qualities of the excipients | | | | Qualities of the excipients |
| | | | | Structural formula and definition of the substituents |
| | | | | Or IUPAC nomenclature |

Note: For instance, if the essential technical characteristic of the composition is the active compound, the examiner will not require that other structural characteristics be mentioned.

- Functional technical characteristics

The functional technical characteristics are the elements that conform the inventions described in terms of their use or function. They do not define the invention but explain the relation between their diverse structural characteristics. For example: device that has an "element to measure the pressure" as well.

The claims must include structural and functional characteristics when the functioning of the characteristic elements and the relation among them is not obvious for a Person skilled in the art. For example: (the underlined text refers to the functional characteristics)

1. Corkscrew, characterized for having a body or central spindle (1), with a spiral thread in its middle part (3), said thread being retractable using a grip axis (2); and at the end of this main body there is another axis (7) along which a pivoting tooth-like protrusion arm (8) in a convex shape(17) is driven up or down to serve as a support to the bottle neck with slotted sides that face each other (12) along which the extensions of the mentioned axis slide (7). [Note of the translator: a description of the corkscrew, as per the patent registration, is included in this web link: http://www.patentgenius.com/image/6799490-4.html]

On the other hand, the claims can include structural and functional characteristics when the functioning of the characteristic elements and the relation among them is obvious for a Person skilled in the

art. For example:
1. A stable pharmaceutical composition that comprises a derivative of the azetidine: N-{1[bis(4-chlorophenyl)methyl] azetidine-3-il} N-(3,5-difluorophenyl) methanesulfonamide in a system that comprises a non-ionic hydrophile surfactant capable of solubilizing the derivative of azetidine and of producing the formation of a colloidal system, and a second lipophilic excipient that stabilizes the formulation.
As it was explained before, both cases are different situations as it can be observe in the examples. In the first case, it is mandatory and in the second optional according to this:

| Cases in which the functional characteristics | |
|---|---|
| Must be included | When the functioning of the characteristic elements and the relation among them is not obvious for a Person skilled in the art. |
| Can be included | When the functioning of the characteristic elements and the relation among them is obvious for a Person skilled in the art. |

**2.6.5.5 Differences between the claims and the description**

The verbal difference occurs if the description says that the invention is limited by certain characteristics, and the claims are not limited similarly. These differences are solved by notifying applicants for lack of clarity and encouraging them to modify the description or the claims to make them coincide.
If the claims do not mention a technical characteristic that according to the description is essential to implement the invention, then the claims are not consistent with the description. In this case, the examiner should require a change to the claims to include this characteristic.
If the claims mention general phrases that suggest inaccurately that the protection is extended to other possible variations or modifications, or that other product is protected, too, when the claims refer only to a procedure, the claims are not consistent with the description, as well; then, it is necessary to clarify it or delete it.

The examiner must revise that a claim that contains a disclaimer (or negative limitation) complies with the clarity and conciseness requirements.

**2.6.5.6 Trademarks or commercial identifiers.**

The examiner must consider that the trademarks or trade names define products or processes that may change through time, although they may keep the name. Therefore, their use in a claim is not permitted because they make difficult to understand the scope of the claim.

**2.6.5.7 Optional characteristics in a claim**

Expressions like "preferably", "for example", "such as", and "especially" 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 (particularly when analyzing novelty and inventive step). If they create confusion in the claim, the examiner must inform the applicant about the lack of clarity and suggest that the optional or preferred characteristics become a dependent claim.

**2.6.5.8 Claims defined by the result expected**

As it was mentioned before, the claims must define the invention for its structural, essential technical characteristics. The examiner must not admit that the claim define the invention for the result expected (like: "Distillation device characterized for having an output of 99 %"), because, in fact, this would be equivalent to defining the technical problem to be solved and the scope of the claim would include not only the solution given by the applicant but all the present or future alternatives that achieve that result.

The result expected/to be achieved is not a technical characteristic of the invention. It can be mentioned in the claim but always together with the technical characteristics that define the invention.

**2.6.5.9 Definition per parameters**

A product claim –e.g. a chemical compound– can be characterized as a product of a process for its structure and elements, its chemical formulation, or, exceptionally for its parameters.

The parameters are characteristic values of measurable properties (For example, a fusion point) or defined as mathematic combinations of several variables.

The examiner will not allow the characterization of a chemical compound only for its parameters unless the invention cannot be defined in a different way. In any case, the parameter has to be determined and measured without ambiguity using standard known methods in the respective field or described clearly in the application.

The same applies to a characteristic linked to a procedure that is defined using parameters.

If unclear or unusual parameters are used, the examiner must require clarification of those parameters; for example, a comparison with known parameters, provided this does not extend the content of the original application (Art. 34). The parameters must be determined clearly, precisely, and unmistakably using objective procedures commonly found in the state of the art. The method to measure the values of the parameter must be included in the claim except when a knowledgeable person in the corresponding field knows the method to be used or when all the methods obtain the same result.

**2.6.5.10 Product defined per the manufacturing process**

The product claims defined in terms of a manufacturing process are admitted only if the products as such comply with the patentability requirement, that is, when they are new and inventive or when they cannot be defined for their structural characteristics. A typical case is the polymers. The preferred redaction is: “Product X that can be obtained using Process Y”.

A product is not new simply for being produced using a new procedure. So that the examiner will object to the lack of novelty of the product and examine if the procedure is new or inventive. For example, if a procedure to synthesize a known product such as the aspirin is claimed, the examiner must determine if the procedure is new and inventive; however, the examiner will take into account that the product claim (aspirin) is not new although the procedure may be new and inventive.

For example:

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Polymers:

Claim 1. A polymer containing tungsten and/or molybdenum metal atoms chemically bonded in the polymer chain obtained by reacting either a saturated or an ethylenically unsaturated dicarboxylic acid or anhydride with a metal complex which is a reaction product of tungsten carbonyl and/or molybdenum carbonyl 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 said complex to obtain a product containing terminal carboxylic groups, and thereafter copolymerizing said product.

Claim 4. A polymer as defined in claim 1 further reacted with a

crosslinking agent to form a thermosetting resin.
Claim 5. A resin obtained by reacting the polymer of claim 1 with a polyalcohol crosslinking agent.
CO 07-79127
Claim 1. A process for the oxidation of carbohydrates which comprises the steps to provide a carbohydrate and combine said carbohydrate with a selected oxidizer of hypochlorite characterized for exposing the carbohydrate and the hypochlorite to ultraviolet light, under alkaline conditions with a pH of 8 or more.
Claim 2. Oxidized carbohydrate obtained through the process described in Claim 1.

**2.6.5.11 Procedure defined by the product**

For example: if the claim mentions a procedure to obtain the compound of formula I characterized because R means hydrogen, chlorine, or alkyl, and R1 means hydrogen, oxygen, or nitrogen; the examiner will require the applicant to define the synthesizing procedure as per its stages and not the characteristics of the product to be obtained.

**2.6.5.12 Use claims**

The claims which preamble mentions the use of a specific product or procedure are not patentable because the uses are not comprised within the patentable matter in Colombia; likewise, a new use of a product or procedure is not patentable because said product is known in the state of the art and because the simple condition of attributing a different use to that patented at first does not mean that a new patent must be granted thereto.

The examiner must issue the respective requirement informing the applicant that the uses are not patentable as per Art 14 d 486; in case of second uses, the examiner must issue the requirement under Art. 221 D 486 and demonstrate that the product or procedure is included in the state of the art; therefore, the respective novelty analysis must be performed (Art. 16 D 486)

**2.6.5.13 Definition stated from referring to a particular use**

The examiner must keep in mind that if a claim defines a product from referring to a particular use, this claim will be considered a use and, therefore, will not be patentable in accordance with Art. 14 D 486.

For example, a claim for "a transistor to be used in an amplifying circuit" will be equivalent to a use claim of the transistor; consequently, the examiner will issue a requirement informing the applicant that uses are not patentable under the mentioned article.

Other example: a form claim for "substance X to be used as an

insecticide" must be considered a use claim; as a result, it will not be patented either.

**2.6.5.14 Reference to the description or drawings**

The claims must not refer to the description or drawings, unless it is strictly necessary. The examiner must not admit expressions such as "as it is described on page 3", "in accordance to example 4", "as it is shown in Fig. 7", in which case he/she must issue the respective requirement. One exception is the case of a piece shown in a figure and which form is impossible to describe with words; so a reference sign to said element but not the figure must be indicated.

If the claims need to refer to the drawings to improve clarity, the presence of reference signs is allowed between braces or parenthesis, after the characteristic mentioned in the claim.

**2.6.5.15 Definition per function**

The claim that mentions an element related with its function without mentioning the structure is deemed to be referring to every element that allows complying with the function, unless said element is described in the claim.

For example, if a claim describes a valve that allows reducing the movement of a fluid, the examiner must consider that said claim comprises the valve as it is characterized in the claim and not all the means that allow reducing the movement of a fluid.

Likewise, a claim for a "construction material that comprises a thermal isolation layer" should be interpreted as it is referring to any construction material that contains "a thermal isolating layer". Then, the examiner must issue a requirement due to a lack of clarity of the claim because it does not define the construction material that is seeking protection, which could be a block, brick, plate, division, etc.

**2.6.6 Conciseness**

The examiner must evaluate the conciseness requirement both to each individual claim and to the group of claims. The purpose of this conciseness requirement is to avoid an excessive complexity for the examiner when analyzing the claims and avoid that third parties cannot see clearly the scope of the claims due to a large number of them and an excessive complexity.

In this way, when the examiner observes that some words are repeated needlessly or there is an excessive number of unnecessary claims, a requirement must be issued for the lack of conciseness.

If there is high number of independent claims that could be reformulated as dependent claims or with the same scope, the examiner

must object to the lack of conciseness.
Regarding the dependent claims, their function is to avoid needlessly repeating all the characteristics in each claim. The number of dependent claims must be reasonable in line with the alternatives to be protected; the examiner must object to the multiplicity of trivial claims.

**2.6.7 Support in the description**

The examiner must keep in mind that the claims must be clear and brief and be supported in the description.
Each claim must contain the technical solution that they are intending to protect; and a person knowledgeable in the field should be able to perform it directly or through the escalation of the content disclosed in the description.
The claims are usually the widening of the content disclosed in the description. Said widening cannot go beyond the scope of that content disclosed in the description. A widening is allowed provided it covers all specific variations or modalities disclosed in the description. To determine if the escalation is appropriate, the examiner must base on the state of the art. If the invention corresponds to a new technological field, the escalation can be broader than when the invention is related with an advance in the current technology.
The general claims in generic terms, the examiner must examine if they are supported in the description. When the claim includes a broad generalization and the technical effect is difficult to be determine, the examiner can consider that the scope goes beyond the content disclosed in the description.
If the examiner finds that one or more specific terms or options included in the generic terms do not solve the technical problem with the suggested solution or achieve the same technical effects, then the examiner must conclude that it is not supported by the description. In this case, the examiner must invite the applicant to modify the claim by restricting it.
For example, when the claim is a broad generalization consisting of a "Method to treat plant seeds consisting of…" and the description contains solely a method to treat seeds of a certain kind of plant without including any other kind, and a Person skilled in the art cannot derive the treatment for the seeds of other kind of plants, the examiner must, in this case, consider that there exists a lack of support in the description. It could only be thought that exists support in the description if the description mentions a relation between this kind of plant's seeds and the seeds of the other kinds,

so that a Person skilled in the art can use this method to treat all kinds of plant's seeds.
In these cases, the examiner must invite the applicant to restrict the claims.

**2.6.7.1 Generalizations**

The generalizations could be made using generic terms, that is, relative to an entire king. For example: "C1-C4alkyl" for methyl, ethyl, propyl, and butyl groups or using parallel options and connecting them using the words "or" or "and", among which at least one option must be chosen. For example, "Characteristics A, B, C, or D" and the substance selected from the group consisting of A, B, C, and D.

**2.6.7.2 Extension of the generalization**

The specific option in the type of parallel option generalizations must be comparable to the content of each other.
A generic term cannot be connected in parallel with a specific term with the word "or". Additionally, the meaning of the parallel options must be clear. Example: A, B, C, D, or equipment, substance, etc. is unclear.

**2.6.7.3 Objection for the lack of support**

In general terms, a function or effect characteristic is not allowed to define the invention. It will be permitted only when the technical characteristic canno be defined para a structural characteristic and when the function can be verified through experiments disclosed in the description or through regular means in the technical field of the invention.
The examiner must consider all the content of the description when verifying whether the invention claimed is supported in the description or not. Moreover, when the description discloses the best way to carry out the invention, he/she must verify if the generalization of the claims can be established using examples, based on the information supplied in the description, and/or using the routine or analysis methods; otherwise, the examiner must conclude that the claims are not supported in the description; then the examiner can encourage the applicant to explain how a person trained in the field, with the content of the description, can extend the invention to the scope claimed; on the contrary, the examiner will encourage the applicant to restrict the claim.
The support in the description must follow technical character; it must not be redacted using indistinct terms without technical content. All the claims, either independent or dependent, must be supported by

the description, and the examiner must verify that.
The examiner must remember that in addition to the objection for lack of support in the description, there could also exist an objection for insufficient disclosure to execute the invention by a Person skilled in the art.

**2.7 Description**

The examiner must keep in mind that the patent application must include a clear description of the invention to allow a Person skilled in the art to understand the technical problem that it intends to solve and what is the solution offered by the application to carry it out.
The examiner must remember that the description of the invention is addresses to the person skilled in the art. So the description must be written as clearly that a Person skilled in the art can understand what the technical problem to be solved is and what the solution offered by the application is; and, also, the description must contain enough information to allow a Person skilled in the art to execute the invention step by step. The two requirements (clarity and enough information) will complement each other.
The description will include the name of the invention and the following information:
- The technologic sector to which the invention refers or is applied to.
The description of what is known helps the contextualization of the invention given that it determines the technical field to which it belongs.
- The prior technology known by the applicant and useful for the comprehension and examination of the invention and the references to the documents and previous publications related to said technology.
It is important to mention the relevant state of the art known by the applicant that can be useful to understand the invention and its relation with the previous art. For example, if the inventor has based on a description of the previous art to achieve the invention, the cited documents can demonstrate the characteristics or stages of the art invented that were already known.
- A description of the invention in terms that allow the understanding of the technical problem and the solution offered by the invention by presenting the differences and eventual advantages in respect to the prior technology.
When the invention refers to a product or a procedure related with a biologic material, and the invention cannot be described in a way to

allow the understanding and to facilitate its execution by a Person skilled in the art, the description will have to be complemented by a deposit of biologic material.

- A description about the drawings, if any.

If there are any drawings, they must be described briefly in the description and must be consistent between each other regarding the signs, symbols, or reference numbers.

- A description of the best way known by the applicant to execute or execute the invention, using examples and references to the drawings, if pertinent.

Regarding the best way to execute the invention, the examples will be considered as particular cases that help to illustrate the best way known by the applicant to execute or carry out the invention. Given that the application is addressed to the knowledgeable person in the technological field, it is unnecessary or undesirable to include characteristics or detail that are well known; on the contrary, it must disclose essential characteristics to carry out the invention without requiring an inventive effort beyond the ordinary skills of that person.

- Mention the way by which the invention satisfies the condition of having and industrial applicability, if it could not be inferred from the invention’s description or nature.

The description must explicitly describe the way in which the invention can be used in the industry, if this were not obvious in the invention’s description or nature.

The examiner must not deny a patent application just because the description is not clear or the information is not enough.

**2.7.1 Clarity**

To fulfill this requirement, the description must include only those details that are actually necessary to define and understand the invention and its diverse modalities.

The description is redacted for knowledgeable people in the specific technical field keeping in mind that their knowledge level is higher than that of the public in general but does not exceed the expected level of a duly qualified person; consequently, the detail explanation of conventional and habitual techniques should not be repeated.

The description must be written using a common language of the technical field to which the invention belongs. If a term has a different meaning from that that is commonly used in the technical field, the meaning must be explained, and the signs and symbols accepted in the mentioned field for the mathematic and chemical

formulae must be used. The measuring units must explain their correspondence with the International System of Units (SI).

If the object of the invention is a new process to synthesize a compound, the description must mention the stages and essential conditions of the compound synthesizing process. Otherwise, an objection for lack of clarity might occur.

If the object of the invention is new compounds, the description must show concrete formulae of the compounds. Otherwise, an objection for lack of clarity might occur.

The use of proper or generic names, trademarks, or similar names to refer to the object matter of the invention is not allowed in the description, unless they are defined therein.

**2.7.2 Sufficiency**

The examiner must keep in mind that the description must contain enough technical information to allow a person moderately knowledgeable in the matter carry out (or reproduce) the invention which should be possible without needing extra inventive effort beyond the ordinary skills. Therefore, if the description omits necessary information to carry out the invention and that cannot be replaced by the knowledgeable person's general knowledgeable, the invention will be deemed as insufficiently described.

The invention will be sufficiently described if the following information is supplied:

- One single example or a reasonable number of examples, alternative execution modes, or variations that enable knowledgeable people in the field, with their general knowledge, to carry out the invention in the entire claimed area and not only in some particular species claimed, without having to put extra inventive effort. In such case the presentation of examples related with all the invention particular species will not be a necessary condition for the sufficiency, provided said species are mentioned in the description.

But the invention can be insufficiently described if the claims' field scope is so broad and the number of examples, alternative execution modes, or variations is not enough to cover the area protected by the claims to a point in which people moderately knowledgeable in the field could not reproduce the invention claimed; therefore, it will be considered that there are just few execution modes sufficiently described. Hence, the description does not fulfill the sufficiency requirement, and part of the claims are not supported in the description.

In such case, the inclusion of examples or characteristics in the

description should not be required because that implies an extension and said modification would be contrary to the current legislation.

**2.7.3 Sufficiency and clarity of Markush formulas and compounds.**

If an application refers to an "A-B-C-D" type Markush formula, the examiner can file a requirement expressing that the information in the description is insufficient to synthesize all the compounds formed by the combination of the formula variables and can suggest the applicant to limit the application.

If the object of the application is a new compound, the applicant has the right to claim the pharmaceutical compositions characterized for containing this new compound; but the applicant is not commanded to use examples on how to design and prepare concrete compositions that contain the new compound because "the solution offered by the invention", that is the object of the invention, is "the new compound" and the person knowledgeable in the field has the capacity to design and prepare concrete compositions containing the new compound, with the information disclosed in the application and their general knowledge. In such case, it will be considered that the description fulfills the sufficiency requirement.

Likewise, if the object of the application is a new compound, the applicant has the right to claim the synthesizing or obtaining process of the new compound. In such case, sufficiency will be achieved provided the applicant has described the stages involved in the synthesizing process.

**2.7.4 Measuring methods and reference signs**

Regarding the measuring methods, the examiner must remember that there are special cases in which a product can be characterized only for a parameter; in such cases, the measuring method of the parameter must be sufficiently described, unless knowledgeable people in the field know the method that must be used because there is one single method or because it is commonly used or the other methods obtain the same results.

On the other hand, the examiner must remember that each part of the drawing must be explained in the description and listed using a reference sign or number; therefore, they must correspond to each other so that all the reference numbers listed in the description must appear in the drawings.

**2.8 Title of the application**

The title of the application must coincide with the object disclosed in the description and be brief and descriptive. The title should not

contain subjective or ambiguous terms or words or include trademarks or names that would not convey a commonly known meaning. If the title refers to topics excluded or exempted from patentability, the examiner must suggest to modify it to adjust it to the product and/or procedure categories.

**2.9 The drawings**

The main purpose of the drawings or figures and graphic representations is support the understanding of the invention and object claimed. The graphics, schemes of a procedure stage, and the diagrams are considered drawings.

The examiner must verify that drawings have the following characteristics:

- They must relate directly with the description.
- They must show the execution forms described.
- The relation between the description and the drawings must be established using reference signs or numbers contained in both elements (description and elements) and correspond to each other. All the reference numbers stated in the description must appear in the drawings.
- Reference symbols or numbers not mentioned in the description must not be used.
- If the description mentions some figures, they must be included. Therefore, no figures or drawings must be included if they have not been described.
- They must be individually and consecutively numbered; the numbering is different to that of the pages.
- They must be done following the technical drawing rules, use durable black lines and strokes, and be sufficiently dense and well outlined. They must not be freehand drawings.
- Drawings should not contain texts or signs. Except for one or two words, when absolutely necessary, such as: “water”, “closed”, “section as per AB”, etc.; and in the case of electrical circuits, schematic installation diagrams, and flowcharts some necessary key words for their comprehension.
- Drawings must be presented in one side of paper sheets and be the same size of the rest of the application documents; drawings must not be contained inside frames or outlines.
- Transversal sections will be shown using diagonals that do not block the main lines or the reading of the reference signs.
- Sections must be indicated using a diagonal line patterns (for the

solid parts) and white spaces (for the hollow parts).
- Sections must be appointed using lines that allow the reading of the reference signs and the directrixes.
- The scale of the drawings and the clarity of their graphic execution must allow distinguishing easily all the details even if copied/reproduced.
- Characteristics of a drawing must not be named by a reference if said characteristic has not been described. That situation may occur when changes to the description have been made; in this case, the applicant is required to delete such reference from the drawing.
- If for any reason the applicant has removed a figure or drawing, the applicant must remove the reference signs of said figure, as well, that are in the description and in the claims, as the case may be. In this case, the examiner must not be too rigorous.
- The scheme diagrams and flowcharts, as well as the chemical and mathematical formulae that are not printed within the description text, are considered drawings.
- Letters and reference numbers in the drawings must be clear and legible; no brackets or quotation marks associated to numbers or letters can be used.
- The reference signs must be identical for the same elements in all the parts of the application.
- They must be presented in paper sheets of the size required, on one side, without using frames.
- If the quality of the original drawings is not good enough, the examiner will require the applicant to file drawings with good quality to obtain good copies, when necessary. However, the examiner should take care with possible extensions of the original object of invention. If the drawings were filed after the application filing date, the examiner should evaluate, first, whether the drawings constituted an important part to understand and execute the invention; this drawings should be filed to comply with the minimum requirements to grant the filing date; in this case this would imply modifying the filing date, and the priority, if claimed, would be affected, as well; second, if the examiner considered that drawings are unnecessary to understand and carry out the invention, he/she must analyze if the disclosure filed at first would be broadened by including drawings, in which case they will not be accepted. In special cases, the form examiner may require the opinion of the content examiner about these circumstances.

## 2.10 Search of state-of-the-art documents

### 2.10.1 Search of priorities (previous registrations)

The search is done essentially to find the state of the art and to determine if the invention claimed is new and has inventive step.

The search performed during the content examination is done online in patent documents of several countries. In addition to the search in patent documents, the examiner searches also in non-patent literature including, mainly, hard copies or electronic national or international scientific and technology magazines, journals, manuals, etc.

The examiner must look up all the patent document (including the equivalent documents in international offices in USA or Europe) and relevant non-patent literature of the technical field to which the invention belongs, or analog fields disclosed before the filing or priority date, if the latter was claimed.

Also, for the purpose of the novelty study, the examiner must search all the applications in process that belong to the same technical or analog field that have been filed before the filing or priority date (as the case may be) and published during the 18 months. The search must include also the PCT applications that have entered the national phase and that are in the same situation.

The following steps must be taken into account to perform the search of priorities:

- The examiner must analyze the documents cited in the application's description which correspond to the basis of the application's object, documents of the prior art related to the technical problem that will be solved or those who help the correct understanding of the invention claimed.

If those documents are necessary to understand the invention and the search cannot be done without them and they are not available in the office, the examiner must ask the applicant to provide a copy. Now then, if the documents cited in the description are not relevant, the examiner can ignore them.

If the applicant has provided the search report of other countries, the examiner should revise them particularly if they can affect the novelty or inventive step of the invention claimed.

- Access the web pages of the offices in Europe and United States to check the documents cited in the searches performed by them and determine if said documents are useful to study the application's patentability.
- The examiner must do the ICP based on the object of the application and following the classification rules.

As the form examiner normally assigns a provisional ICP, whoever does the search determines if said ICP is appropriate; if not, he/she will assign it. If the examiner also notices that the invention belongs to other technical field, but in any case has to examine the application, he/she will seek help from the other field's examiner to assign the correct ICP.
Example of a search:
If the examiner is searching a cosmetic formulation in the form of a liposome to treat skin against premature aging, he/she can use ICP to limit the search in order to find patents related with the cosmetic formulation that contain liposome by finding these classifications:

Section A: Human Necessities
Class A61: Medical or veterinary science; hygiene
Subclass A61K: Preparations for medical, dental or toilet purposes
Main group: A61K 8/00 Cosmetics or similar toilet preparations
Subgroup: 8/02: characterized by special physical form
Subgroup: A61k 8/14: liposomes: this subgroup is specific to 8/02.

Section A: Human Necessities
Class A61: Medical or veterinary science; hygiene
Subclass A61Q: Specific use of cosmetics or similar toilet preparations
Main group: 19/00 Preparations for care of the skin
Subgroup: 19/08: anti-aging preparations
So the search starts using the code of the subclass A61K. If there are too many documents, you can use the codes of the main groups or subgroups; that is, you can use the codes A61K 8/02, A61K 8/14, A61Q 19/00 A61Q 19/08.
On the other hand, there are 4 main perspectives to look up information about patents in databases as follows:
- Thematic links: you need a base document to find other documents related with the subject matter.
- Key word: to find documents related per key word and not per explicit reference. Various key words that describe the important characteristics of what is being searched must be determined.
- IPC: the International Patent Classification can help the search of patent bibliography, and several databases can be looked up using this classification.
- Chemical structure: it recognizes the main nucleus of the compound being searched. The results can include similar names and magazines

where said chemical compounds are mentioned.
Combined techniques of these approaches are also used to improve accuracy of the search.

**2.10.2 Determine the technical field that must be searched**

The examiner usually has to perform the search in the technical field to which the object of the application belongs. When necessary, the search can include analog technical fields. The technical field to which the object of the application belongs is determined as per the content of the claims.
When defining the analog sectors to which the search must be extended, it is important to keep in mind the following:
- Sectors in which a knowledgeable person in the matter could use the same or similar structure in different works or for different uses;
- Sectors to which a generic concept of the characteristics claimed belong
- Proper techniques of the sector in which the efforts of the inventor have focused and are sufficiently related with the particular problem that the inventor has faced;
- Sectors related with the function or use of the object of the claims, that is, the most probable application field of the invention and the general field to which the object of the search belongs that would be the object of said search.

The decision to extend the international search to sectors not mentioned in the international application is discretional to the examiner who, nevertheless, must not try to imagine all the possible applications of the invention claimed that the inventor could have dream up. The decision to extend the search to analog sectors must be based mainly on the question if it is probable to find, in said sectors, elements to establish validly an objection founded in the lack of inventive activity.

**2.10.3 Determine the basic elements of the search**

After analyzing the application documents, understanding clearly the content of the invention, and determining the IPC and the technical field to be searched, the examiner must analyze the claims to establish the search elements.
To determine them, the examiner must, first, analyze the technical solution defined in the independent claim and then determine the search basic element that can be contained in the technical solution. The basic elements of the search can be established based on the technical fields, problems, effects, etc.

### 2.10.4 Search object

#### 2.10.4.1 Text of the application for searching purposes

The text of the application that must be considered for the search includes the description, claims, and drawings, if applicable, filed at first by the applicant when filing the application. The text to be taken into account is the last provided by the applicant, if changes to the description and/or claims have been done either to fulfill a requirement of the office or when they have been done at discretion of the applicant in compliance with that established in Art. 34.

#### 2.10.4.2 Search of independent claims

The examiner must determine first if the independent claims correspond to non-patentable matter, in accordance with Articles 15 and 20; in this case no search is necessary.

The search must be done based on the invention defined by the claims and supported by the description and drawings, if applicable, because the claims determine the scope of the protection.

The examiner must take the technical solution defined in the independent claim as the search object. The search must focus on the inventive concept of the independent claim and not on its literal redaction. However, the search must not be extended to include every single detail that can derive from a consideration of the description or drawings.

#### 2.10.4.3 Search of dependent claims

If after a search addressed to the invention defined by the independent claim the outcome is that it is not new or has inventive step in order to evaluate whether the technical solution comprised in the dependent claims is new or has inventive step, it is necessary to extend the search taking the dependent claims as the search object. However, it is unnecessary to extend the search if the additional characteristics of the dependent claims are widely known.

As a general rule, if the outcome of the search reveals that the invention defined in the independent claims is new and has inventive step, it is unnecessary to extend the search to the object described in the dependent claims as such.

#### 2.10.4.4 Search of claims characterized by a combination of elements

In the case of claims characterized by a combination of A, B, and C elements, the examiner must aim the search, first, at the combination A+B+C; if the novelty or inventive step is not affected, the examiner must also aim the search at their sub-combinations A+B, B+C, A+C, as well as to the individual A, B, and C elements.

**2.10.4.5 Search of claims from different categories**

When the application contains claims from different categories (product, process, device), the examiner must aim the search at each of these claims. In some circumstances, although the application contains claims only of a same category, it might be necessary to aim the search at other categories. For example, when the search is aimed at a claim for a chemical process to determine its inventive step, in addition to the search done for the process claim, the search must also cover the final product made through the process unless the product is obviously known.

**2.11 Unity of invention**

**2.11.1 What is unity of invention?**

The application must be related with a single invention; or in case of a group of inventions, they can only be object of the same application if they are so linked between them that they form a single general inventive concept.

Unity means that an application can contain one or more inventions only if they belong to a single general inventive concept.

"Single inventive concept" means the group of new technical or inventive characteristics (or elements) that are common to all the inventions.

The unity requirement must be fulfilled for the following reasons: a) economic, to avoid that the applicant obtain protection for various inventions while paying fees for just one patent; and b) technologic, for the benefit of the classification, search, and application's examination.

The lack of unity of invention occurs a priori or a posteriori:

- A priori means that the lack of unity of invention is evident prior to the search in the state of the art if no single common inventive concept exists; that is, one or some new and inventive technical characteristics (or elements) that are common to all the inventions.

For example, in the case of the following independent claims,

Claim 1: a reaper

Claim 2: an herbicide

At first sight, no single common inventive concept exist because there are not new or inventive technical characteristics in common for the reaper and herbicide.

Then, the examiner can conclude, before the search (a priori) that no unity exists.

- A posteriori means that the lack of unity of invention is evident

after the search in the state of the art, if no "new or inventive technical characteristics" that are common to all the inventions are found.
So, if the search in the state of the art shows that the technical characteristics (or elements) that are common to all the inventions are not new or inventive, they are not the only inventive concept and no unity of invention exists.
The common technical characteristics can be identical or correspond to each other.
The corresponding technical elements are those that are not identical but solve the same problem. They can be
Alternative elements that achieve the same effect (Markush alternatives);
Complementary elements that separately contribute to a particular effect;
Complementary elements that separately contribute to a particular effect;
Cooperative elements that produce only one effect when operating together; or
"Specially-adapted" or "specially-designed" elements for elements of other inventions.
The lack of unity of invention normally occurs a posteriori, that is, as a result of the search because most of the time it is possible to determine if the technical characteristics (or elements) that are common to all the inventions are new or inventive only after revising the state of the art related with the inventive concept. As a result, most of the unity examinations can be done only a posteriori.
The examination implies an a posteriori invention unity study, i.e. considering the closest state of the art in order that the examiner can determine whether there are documents that foresee the technical characteristics that define the single common inventive concept and, in such case, conclude that there is not a single common new or inventive concept for the group of inventions claimed.

**2.11.2 Evidence that there is a lack of unity of invention**

The following case are evidence of a lack of unity:
- Some independent claims of the same category have different technical characteristics.
- There is a very broad independent claim.
- It is necessary to search in diverse technical fields.
- There is evidence of various problems that are unlikely to be related
- A document in the state of the art destroys novelty of just one

independent claim.

**2.11.3 Method to examine the unity of invention**

If the examiner considers, at first sight, that it is possible for the application under study to lack unity of invention, he/she must follow these steps:

- Identify the invention mentioned first and identify its essential technical characteristics. The invention mentioned first is:

O Claim 1

O The first alternative if the object of claim 1 is expressed using alternatives; or

O The first example in the description

- Identify the other possible inventions and their essential technical characteristics
- Do the search and examine novelty and inventive step of each possible invention using the problem-solution approach.
- Compare the objective technical problem and the essential technical characteristics of each possible invention

If the possible inventions solve the same objective technical problem and have common essential technical characteristics, and these characteristics are the single common inventive step of the inventions, the examiner will conclude that there is unity of invention.

If the possible invention do not have common essential technical characteristics, the examiner will conclude that there is not unity of invention.

These pre-established particular situations exist, as well, when examining the unity of invention:

- A combination of claims of different category;
- The "Markush practice";
- Intermediate and final products;
- Combinations

**2.11.3.1 Combination of claims of different category;**

The examiner must keep in mind that the following cases have unity of invention and, thus, he/she can include any of the following combination of claims of different category within the same application:

- Product and procedure:

O Independent claim for a PRODUCT and

O Independent claim for a PROCEDURE specially adapted to manufacture said product.

- Procedure and device:

O Independent claim for a PROCEDURE and

O Independent claim for a DEVICE or MEDIUMS specifically design to carry out said procedure.

- Product, procedure, and device:

O Independent claim for a PRODUCT,

O Independent claim for a PROCEDURE specially adapted to manufacture said product, and

O Independent claim for a DEVICE or MEDIUM specifically design to carry out said procedure.

Procedures to synthesize a known product:

No unity of invention exists between the procedures to synthesize a known product, although said procedures might be new or inventive. Each procedure is a different inventive group because the product is not the common inventive concept to all the procedures.

Procedures to synthesize a new or inventive product:

There is unity of invention among the procedures to synthesize a new or inventive product, although the synthesizing routes do not have common technical elements because the product is the common inventive concept to all the procedures.

**2.11.3.2 Combination of compounds.**

The composition contains: a first type of compounds that have a first similar function and a first common structure that, as per the disclosure, it is essential for that first function; and a second type of compounds that have a second similar function and a second common structure that, according to the disclosure, is essential for that second function.

That type of compositions will be deemed to have unity

Example:

There is unity of invention when

The composition claimed contains compound X and a selected compound of the group consisting of A, B, and C.

And the state of the art explains that A, B, and C have a similar function and a common structure that, as per the disclosure, is essential for the function.

The composition contains: a first type of compounds that have a first similar function and a first common structure that, as it is informed, is essential for that first function; and a second, third, fourth (…) type of compounds that have a second similar function but second, third, fourth (…) different structures.

That type of compositions will be deemed to not have unity.

Example:

There is not unity of invention when

The composition contains compound X and a selected compound of the group consisting of A, B, and C.
It is informed that A, B, and C have a similar function but are structurally different molecules.
So there are three inventive groups:
- Group I: composition containing compounds X and A
- Group II: composition containing compounds X and B
- Group III: composition containing compounds X and C

**2.11.4 Procedure/means/communications to inform the lack of unity of invention**

The examiner must write down a requirement supported technically, in case he/she finds that no unity of invention exists; this writing must contain
- A reasoned explanation of the lack of unity, considering the relevant state of the art used to determine the lack of unity.
- A list of each inventive groups of the application, mentioning their differential characteristics.
- The patentability examination (novelty and inventive step) of at least one inventive group.
- A requirement addressed to the applicant giving the possibility to choose from the following options:

O Restrict the application to the first invention or the preferred inventive group.
O File the divided applications that correspond to the different inventions and pay the additional fees.
O State the inventive groups that the applicant considers the application can be divided into.

- If the search and evaluation for the other inventions does not require additional effort, the examiner will file them for all the inventions.

**2.11.5 Procedure that follows the determination of lack of invention**

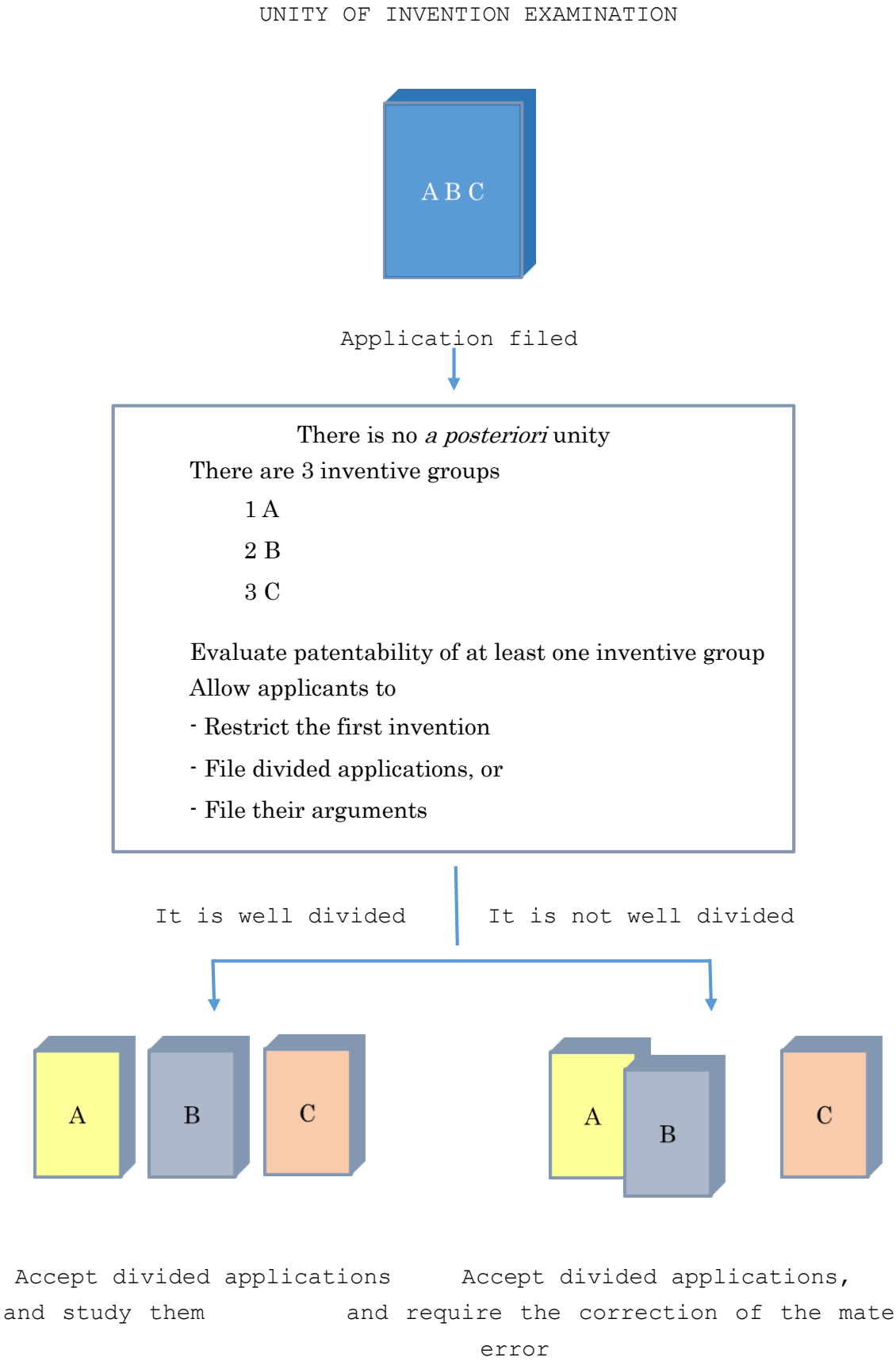
Once the applicant has filed the divided applications as a result of having been informed that his/her application lacks unity of invention, the procedure will continue as follows:
If the examiner considers that the divided applications filed by the applicant in response to the mentioned requirement are well divided, he/she must accept the divided applications.
If the examiner considers that the divided applications filed by the Applicant in response to said requirement are not well divided (according to the groups that he/she mentioned) because they contain, for example, matter that overlaps, he/she must accept the divisional

applications.
And the examiner must issue a first requirement for each divided application, said requirement containing
- A clear definition of the overlapped matter that must be removed from any of the divided applications but can remain in the other, with the purpose of fixing the division.
- The patentability examination (novelty and inventive step) of, at least, the first invention.
The applicant, in response to the requirement, can offer his/her own arguments or remove the overlapped matter from any of the divided applications. After, the examination will continue for each of them separately.
If the arguments filed are turned down, a second requirement will be issued to have one single invention per divided application. In case the applicant did not respond or the lack of unity persisted, the patent would be denied.

**2.11.6 Division of the application (divided applications)**

Each divided application will benefit from the filing date and from the priority date of the initial application, if applicable.
In case of having claimed multiple or partial priorities, the applicant or the SIC will mention the priority dates that correspond to the subject matters that must be covered by each of the divided applications.
In order to divide an application, the examiner must verify that the applicant has submitted the necessary documents to form the corresponding divided applications.

### 2.11.7 Diagram of the unity of invention examination

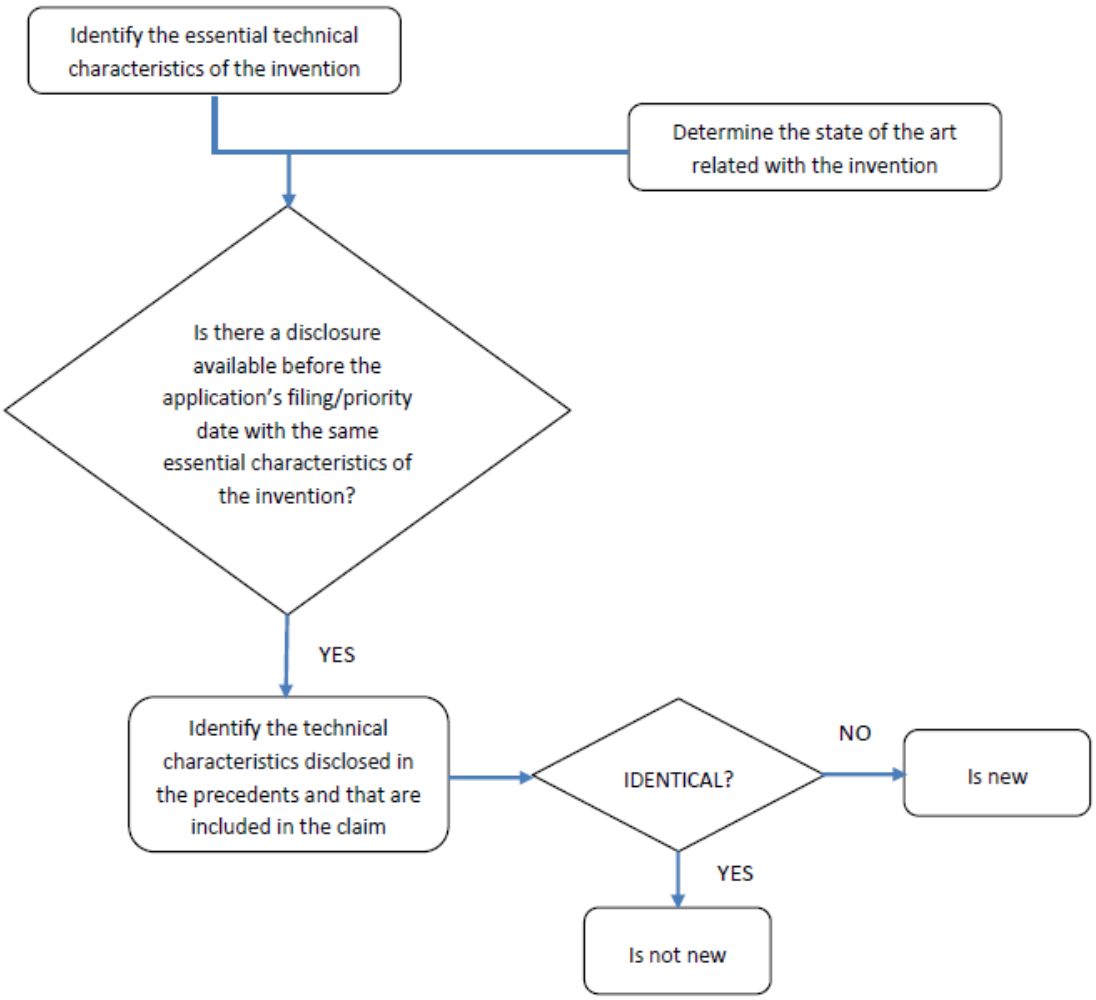


## 2.12 Novelty

The examiner must determine whether the invention is new or not as follows:

- Define what the essential technical characteristics of the first independent claim are;
- Compare the essential technical characteristics, element by element, with the characteristics of the matter disclosed in each document of the state of the art;
- Verify if, under the previous comparison, the invention claimed is identical to what was disclosed in the state of the art in which case it is deemed to not have novelty;
- Examine the other independent claims similarly; and
- Revise whether the dependent claims mention new elements

### 2.12.1 Novelty examination diagram



### 2.12.2 Considerations that are taken into account in the novelty examination

#### 2.12.2.1 State of the art

The examiner must take into consideration that the state of the art is the group of knowledge that has been available for the public through a written or oral description, use, commercialization, or any other means, prior to the filing or priority date.

#### 2.12.2.2 One-year grace period

The examiner does not consider harmful for the novelty examination the disclosure of the invention within one year before the application's filing of priority date if the disclosure is done by the inventor or the national patent office or a third party that has obtained the information directly or indirectly from the inventor or his/her successors.

Also, if the inventor has disclosed the invention within a year before the application's filing date, the examiner must verify that said declaration has been filed in writing and mentions the medium used for the disclosure, the place, and date.

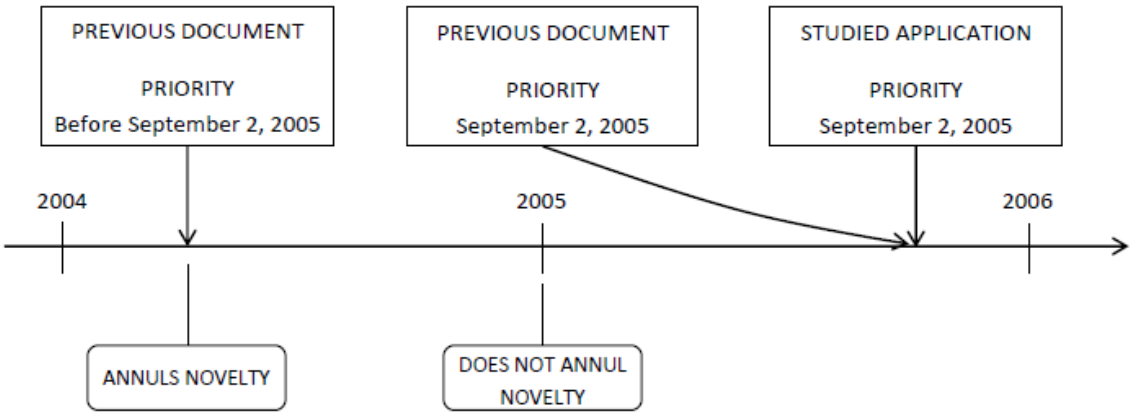
#### 2.12.2.3 Novelty in respect to another prior application under process

The examiner must consider that the content of a patent application under process before the SIC is included in the state of the art, and that the application has a filing or priority date before the filing or priority date of the patent application under examination, only for the novelty examination.

Priority:

The examiner must consider that the applicant has a priority right that consists of the right to file a first invention or utility model patent application, or a registration application of an industrial design in other country.

The examiner must acknowledge the priority right if the first application was filed during the last year before the filing date of the application under study. For example, if the application date is September 1, 2000, and the priority date is after September 2, 1999, this priority document does not annul the priority; but if the application date is September 1, 2000 and the priority date is before September 2, 1999, this priority document annuls the priority. The following diagram illustrates this situation:




The examiner must verify that, in order to benefit from the priority right, the application invoking said right must have been filed maximum during the terms described below as of the filing date of the application which priority is invoked:

a) 12 months for invention and utility model patents; and

b) 6 months for the industrial design registrations.

**2.12.2.4 Combination of documents**

Examiners must remember that to evaluate novelty, they must compare each independent claim with elements of the state of the art, and no combination of elements of one or more documents of the state of the art is allowed.

However, if a document (the "initial" document) explicitly refers to another document (for example, as a document that provide detailed information about certain characteristics) the content of the latter can be deemed as incorporated to the initial document to the extent stated in said initial document.

Likewise, the use of a dictionary or similar reference document to interpret a specialized term used by the initial document as of the publication date is allowed.

Similarly, the examiner can use other documents to demonstrate that one characteristic that was not disclosed in the initial document was an implicit characteristic to that document as of its publication date (for example, a document that demonstrates that rubber is an "elastic material"). The examiner can cite these documents and include the bibliographic citation as a footnote to the technical report.

The examiner must keep in mind that if the information is contained in several parts of the same document, said information can be combined. For example, if the product claimed has 4 elements and the state of the art document shows a product mentioning these same 4 elements in

different parts of the document, the examiner will consider that the product claimed is not new.

It is not permitted that the novelty be refuted based on a general common knowledge of the art that the examiner may know, because said knowledge must be supported by documentation.

**2.12.3 Novelty examination**

**2.12.3.1 Generic disclosure and particular examples**

The examiner must take into consideration that a general expression of the state of the art does not annul novelty of a particular element that is being claimed and included within said general expression.

For example, if an invention refers to a product with "chlorine", and the state of the art refers to a "halogen", this document does not annul novelty of the invention. However, it is important that the examiner remembers that if the state of the art discloses a product with "fluoride", this disclosure in specific terms does not annul the novelty of the invention of a product with "chlorine", either.

On the other hand, the examiner must take into account that a particular element of the state of the art annuls novelty of a general expression being claimed, if the particular element is included in the general expression.

For example, a product made of copper and that is included in the state of the art would annul novelty of the invention of the same product made of metal. However, the disclosure of a product made of copper would not annul novelty of a product made of other specific metal.

**2.12.3.2 Selection inventions**

A selection invention is a patent that claims one single element or a small group of elements that belongs to a broad known group of elements.

If the specific group claimed is not explicitly described in any priority of the state of the art by its name and is far from the examples of the state of the art and the end points, the examiner will consider that said specific group claimed is new (selection).

But if the essential characteristics of the group claimed were disclosed specifically in one single document of the state of the art, the examiner must consider that the claim is not new.

Having accepted the fact that "what is general in the in the state of the art des not annul the novelty of the particular issues claimed, and what is particular in the state of the art annuls novelty of the general issues claimed", the examiner will understand that a product claimed formed by the selection of a specific element, based on a single list of product elements in the state of the art, is not new

because the listing of all the possibilities of a single element is equivalent to the listing of all the specific products.
But a product claimed formed by the selection of two or more elements, based on two or more lists of elements of a product of the state of the art, is new. In such case, the examiner must consider that the selection patent is new since "a general expression of the state of the art does not annul the novelty of a particular element claimed and that is included in the general expression."
However, when the elements of the application and a document of the state of the art overlap, that is, a subgroup of the products claimed is known, the examiner will consider that the claim is not new, even if that document does not disclose some specific product of the subgroup.

**2.12.3.3 Value range.**

If the invention claimed has an essential technical characteristic defined by number values or ranges such as temperature, pressure, content of components in a composition while the other essential technical characteristics are identical to those contained in the document of the state of the art, the following has to be considered to determine the novelty:
When the numeric range disclosed in the document of the state of the art is included in the range that defines the essential technical characteristic, the document of the state of the art annuls the novelty of the invention claimed.
Example: the application claims a composition that comprises 10-35% (weight) of Zinc, 2-8% (weight) of aluminum, and the rest of copper. If the reference document discloses a composition with 20% (weight) of zinc and 5% (weight) of aluminum, the invention claimed loses novelty with the disclosure made in the reference document.
Wherever the numeric range disclosed in a reference document and the range that contains the technical characteristic overlaps partially the other's range and has at least one common final point, the reference document removes eliminates the novelty of the invention claimed.
When the numeric range disclosed in a document of the state of the art overlaps partially with the range that defines the essential technical characteristic and has at least a common end, the document of the state of the art annuls the novelty of the invention claimed.
Example: the application claims a process to make pottery in which the calcination time is 1-10 hours. If the reference document discloses a process in which the calcination time is 4-12 hours, both ranges

overlap each other from 4-10 hours and the reference document eliminates the invention claimed.
Example: the application claims a process in which the power is 25-50 kW; if the reference document discloses a process in which the power is 50-80 kW, in this case both ranges have a common final point of 50 kW; the reference document affects novelty of the invention claimed.
The two final points of a numeric range disclosed in the reference document make the invention claimed to lose novelty when the range of the claimed invention's technical characteristics include one of the final points; but the technical characteristics which ranges are between the final ranges do not lose novelty.
The two ends of a numeric range disclosed in a document of the state of the art annul novelty of the invention claimed when the range of the claimed invention's technical characteristics include one of the two ends; but the technical characteristics which ranges are between the two ends of the ranges do not lose novelty.
Example: the application claims a process where the drying temperature is 40 °C, 50 °C, 78 °C, or 100 °C. If the reference document discloses a process where T = 40 °C – 100 °C, it makes the application lose novelty if T is 40 °C or 100 °C but not if T is 58 °C or 75 °C.
When the range of the essential technical characteristic is included in the range disclosed in the document of the state of the art and does not have a common end, the application does not lose novelty.
Example 1: Diameter is 95 mm. If the reference document discloses a diameter of 70-105 mm, said claim does not lose novelty.
Example 2: the application claims a copolymer ethylene- propylene where the polymerization degree is 100-200. If the reference document discloses that said copolymer has a polymerization degree between 50 and 400, this last does not make the claim lose novelty.

**2.12.3.4 Parameters**

If a product, base product, or manufacturing process corresponds in all its aspects to another from the state of the art, but the claim defines a parameter not mentioned in the state of the art, the examiner must issue an objection for the lack of novelty stating, at first, that the state of the art would probably have the same value for that parameter if it were measured. This will apply especially if the parameter is unusual or unknown.
If the applicant demonstrates that, the parameter is actually different in the invention claimed in respect to that of the state of the art by giving, for example, valid arguments or comparative trials, the novelty would be determined.

For example, if the application claims an alloy that has the same components of a known alloy in the state of the art but is defined in the claim by its fusion point, the examiner must issue a requirement due to a lack of novelty given that the alloy corresponds identically to the alloy of the state of the art and would probably have the same value if its fusion point were measured.

Negative limitations or disclaimers:

In general, the examiner must consider that the object of a claim is defined by the positive characteristics. However, the scope of the claim can be limited by a disclaimer, a "negative limitation", or an exclusion" of an element clearly defined. This is used only when it is not possible to define the object of the claim with positive characteristics alone. Per se, a negative limitation does not have anything ambiguous or vague.

Examples: "cosmetic composition characterized because it does not contain stearic acid", "in which the compound does not contain water", "said homopolymer being devoid of proteins, soap, resins, and sugars present in the rubber obtained from the rubber tree, "not capable of forming a dye/pigment with said oxidized developer."

The examiner accepts a disclaimer in the following cases:

- When it had been disclosed in the description;
- In response to an objection filed:

O To restrict the claim, after the examiner issues his/her objection for the lack of novelty. For example: if the claim filed at first refers to "a compound of formula (I)", and the examiner finds that compound "A", which is included in formula (I), is not new, the examiner will accept a new claim containing a disclaimer for the compound type of formula (I), except compound "A".

O To remove non-patentable matter.

The examiner does not accept a disclaimer of a technical characteristic not disclosed in the application if

- It is filed to exclude variations that do not work or to correct an insufficient claim;
- The exclusion of the characteristic produces a technical effect in a way that the limitation makes the application inventive;
- It supposes an extension of the matter claimed at first.

Example: "cosmetic composition characterized because it does not contain perfume"; but, although the compositions in the description do not contain perfume, they do not expressly mention that the technical effect caused for not containing it is that it does not cause allergies the user.

**2.12.3.5 Implicit disclosure**

The technical content of a document of the state of the art is not only the content expressly disclosed in said document, but also the technical content that a Person skilled in the art can derive directly and without ambiguity from the disclosure.

For example, if the document of the state of the art discloses a racemic mixture, the examiner must consider that the knowledgeable person in the matter can derive directly the optical isomers claimed, which are the specular forms that conform the racemic mixture. Therefore, the examiner will conclude that the optical isomers, in this case, are not new.

**2.12.3.6 Implicit characteristics or their well-known equivalents.**

The examiner, in the novelty examination, must not consider the well-known equivalents disclosed in a document of the state of the art because they correspond to the consideration of obviousness or the inventive step. For example, a copper wire and a silver one are equivalent for having the same function, but they are not the same.

**2.13 Inventive step**

The patent examiner must adopt the stance of a Person skilled in the art that corresponds to the patent application and determine whether for that person the invention filed is obvious or derives evidently from the state of the art.

Novelty or inventive step are different criteria. An invention is not new if each of its elements or characteristics are disclosed explicitly and intrinsically in the state of the art. Therefore, there is novelty if any difference between the invention and the known art exists.

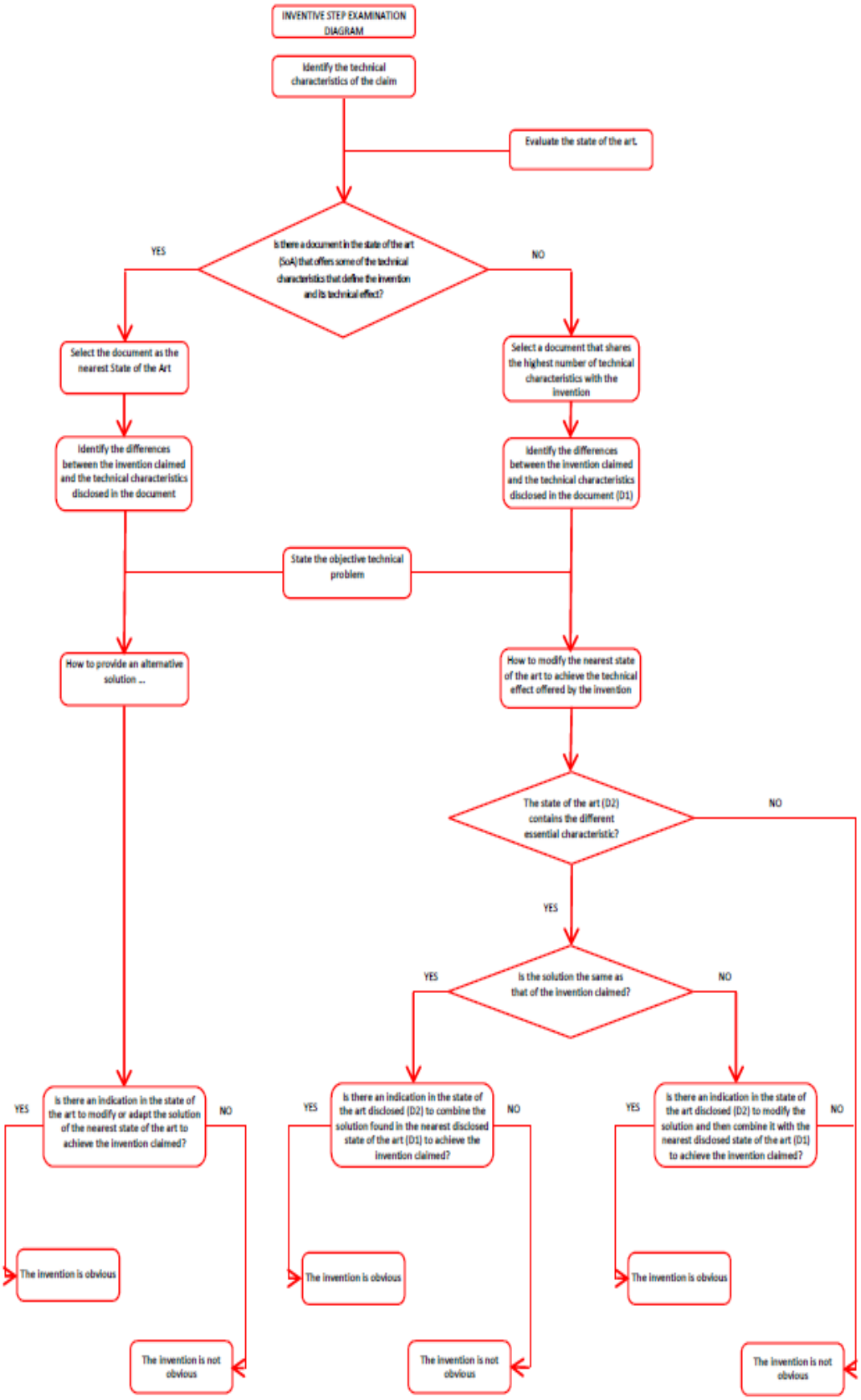
The invention does not have inventive step when the combination of the elements offering the solution is disclosed in the state of the art; that is, the existence of the elements –separately or individually considered to conclude the lack of inventive step- is not enough; conversely, they as a whole must evidently teach the way to reach to the solution to the technical problem.

The question: "is there inventive step?" arises only if there is novelty.

It is important to examiner the inventive step after the novelty because it is easy to fulfill the novelty requirement given that unimportant modifications make an invention new. But the modification must be such that they do not originate obviously from the prior art; that is, they have not "easily" been done by a moderately knowledgeable person in the matter.

If the invention has inventive step, it means that it has one or more characteristics that imply a technical advance when compared to the existing knowledge.

### 2.13.1 Inventive step examination diagram



### 2.13.2 State of the art

If the state of the art teaches on how to derive the solution, revise if the group of instructions given by the state of the art would lead you immediately to the solution offered by the application. If it is necessary to carry out additional steps or steps to prove or overcome obstacles revealed by the proper lessons, then the state of the art does not reveal the solution to the problem.

### 2.13.3 Obviousness

The term "obvious" means that something does not go beyond the development of technology; on the contrary, it simply or logically follows the normal progress of the art; for example, something that does not imply the exercise of any skills beyond what would be expected from a person skilled in the art.

### 2.13.4 Person skilled in the art

A "Person skilled in the art" is a term used to describe a person whose knowledge and skills will serve as a basis to analyze whether the solution claimed implies inventive step or not.

It is assumed that the Person skilled in the art has the average knowledge in the specific technical field of the invention, is not specialized, performs regularly in the field, has normal competencies, and is aware of the common general knowledge in the art (information contained in monographs, dictionaries, text books, etc.) as of the filing or priority date of the application. They are also people who have had access to the knowledge of the "state of the art", particularly, the documents cited in the international search report and have had the media and normal capacity at hand for routine experimentation.

### 2.13.5 Inventive step examination

The examiner must not base on personal appraisals; every objection regarding the inventive step must be proved using documents of the state of the art. That is, the examiner must establish the patentable matter and exclude or reject the non-patentable one, in accordance with the state of the art and conforming to the legislation and the jurisprudence; the examiner must not limit to establish the differences between the application and the state of the art. The method to examiner the Inventive Step is the Problem-Solution approach.

The examiner must file the relevant documents that annul the inventive step of the invention under study, as well as the examination on how the prior disclosures lead a Person skilled in the art to carry out the invention without having to do any research at all.

On the other hand, if the applicant provides information to demonstrate

or prove that his/her invention offers an improved effect versus what is already known, the examiner will have to analyze whether said information constitutes a contribution to the state of the art and, thus, conclude that the invention has inventive step.

**2.13.5.1 Problem-solution approach**

During the inventive step examination, a value judgment must be done, as well as an objective analysis of the prior disclosures of the state of the art, without the influence of the knowledge already offered by the invention under study. Therefore, in order to minimize subjectivity and avoid that a retrospective (hindsight or a posteriori) analysis is done, the examination must relate the invention with the solution to the technical problem using the problem-solution approach. It comprises the following stages:

- Identify the closest state of the art to the invention claimed

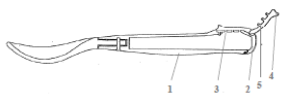
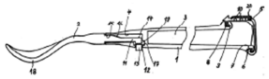
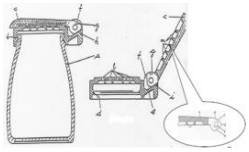
The closest state of the art is a document that exists in the same technical field as the invention or tries to solve the same or similar problem. Often, it is the document that contains more common characteristics with the invention or shows slight structural changes and states the same function or purpose.

In case there are several related documents, the closest state of the art is the document that mentions an activity, function, purpose, or problem to be solved that is similar to that of the invention.

- Determine the difference between the invention and the closest state of the art

Compare the essential technical characteristics of the invention with that of the closest state of the art using a matrix similar to the one shown below:

Comparison of the essential technical characteristics with that of the state of the art:

| **Essential characteristics** | **D1** | **D2** |
|---|---|---|
| Silverware piece that comprises:  | Silverware piece that comprises:  | Salt shaker with a closing element with protrusions that fit into the perforations:  |
| Hollow handle (1) to receive spices | Hollow handle (1) to receive spices (page 5, Fig. 1) | Does not mention a handle |

| | | |
|---|---|---|
| Back cap (2) | Back cap (5)<br>(page 5, Fig. 1) | Cap (b)<br>(page 5, Fig. 1) |
| Containing perforations (3) | Containing perforations (3)<br>(page 5, Fig. 1) | Containing perforations (I)<br>(page 5, Fig. 1) |
| And where a closing element (4) is installed to avoid spice spills | And where a closing element (20) is installed to avoid spice spills<br>(page 5, Fig. 1) | And where a closing element (c) is installed to avoid spice spills<br>(page 5, Fig. 1) |
| The closing element contains protrusions (5) that fit into the perforations when closed. | No protrusions are mentioned. | The closing element contains protrusions (m) that fit into the perforations when closed.<br>(page 5, Fig. 1) |

- Define the technical effect caused and attributable to the differential element

The analysis must focus on the difference, and the effect caused by said difference and attributable thereto must be extracted.

- Deduct the objective technical problem

The examiner must restate the technical problem that the application had mentioned first in the light of the search report.

The objective technical problem is stated in terms of: So the objective technical problem will be expressed as follows: "how to modify or adapt the closest state of the art to obtain the technical effect that the invention provides."

The definition to the objective technical problem is based on concrete objective facts of the state of the art and on the results achieved by the invention.

The expression "objective technical problem" must be interpreted in a broad sense; it does not imply necessarily that the solution constitutes a technical improvement regarding the state of the art because it is possible that the problem consist simply of finding a replacement solution to a device or a known procedure that produces identical or similar effects.

- Analyze if the invention claimed, based on the closest state of the art and the objective technical problem, would have been obvious for a moderately Person skilled in the art

This stage consists of responding to the question if in the state of the art as a whole there is a second document containing guidelines that would instruct the moderately Person skilled in the art, who had to face the technical problem, on how to modify or adapt the closest state of the art to solve the problem as per the claim, without

performing any inventive activities.
If the answer is yes, the invention is considered obvious and, thus, [the examiner] can conclude that it lacks inventive step. Otherwise, the invention is not obvious and is deemed to have inventive step.

**2.13.5.2 Inventive step of dependent claims**

The examiner must remember that a dependent claim contains all the characteristics of the claim from which it depends. Hence, if the independent claim is inventive, its dependent claims are inventive, too.
On the other hand, if the independent claim is not inventive, the examiner must analyze the respective dependent claims to verify if any of them mentions an inventive technical characteristic. If so, the examiner will encourage the applicant to include said characteristic in the independent claim and, as a result, the claim will be inventive.

**2.13.5.3 Evidence**

The evidence are examples of what is commonly considered as inventive or not; the examiner uses them when
- The problem-solution approach has raised concerns;
- The answers of the applicant are analyzed ; and
- The capacity of the moderately knowledgeable person in the files is assessed.

**2.13.5.3.1 Evidence of the existence of inventive step**

It is considered that there is evidence of inventive step under the following circumstances:
- Technical problem unsolved before the invention.
- If the invention claimed solves a technical problem that is intended to be solved since a long time ago without success, the invention has inventive step because it represents a technological advance.
- Overcome a technical prejudice (because the experts are far from the solution); technical prejudice is the fact that the specialists in the corresponding technical field think that there is only one way to solve the technical problem. If the invention is carried out to eliminate that prejudice by adopting technical means that have not been used before, this is evidence in favor of the existence of inventive step.
- Simplicity: replacement of machinery or complicated procedures for simpler versions.
- Unexpected technical effect.
- Overcoming of difficulties that have not been solved yet by the routine techniques.
- Need of more than two documents to examine the inventive step.

- In a process: elimination of a stage that was considered necessary without producing a harmful effect.
- Transference of a way of doing things from a technology field that is not related with the invention.

**2.13.5.3.2 Evidence of the lack of inventive step.**

- Add stages known in processes or use known devices working without changes and unexpected results (juxtaposition).
- Simple and direct extrapolation of known facts.
- Change of size, shape, or proportion obtained through trials but without unexpected results.
- Interchange the material for a different analog one.
- Use known technical equivalents and select between a number of known possibilities without an unexpected result because the outcome could have been foreseen by a Person skilled in the art.
- Known equivalents.
- Selection of similar alternatives similarly probable.
- Simple replacement of a technical characteristic by a different one that is obvious for the knowledgeable person in the matter. For example, replace the material of an aluminum structure by a different material that does not offer a significant advantage.
- Simple substitution of a compound to form a new synergic combination of two specific compounds with a previously knows synergic combination of two categories of compounds.

**2.13.6 Considerations that are taken into account in the inventive step examination**

**2.13.6.1 Combination of documents**

Unlike the novelty examination, the inventive step examination can combine two documents of the state of the art or different carry-out examples or parts of the same document, but only if said combination were obvious for the knowledgeable person in the corresponding technical field.

The maximum number of documents to be combined to examine the inventive step is two. However, the examiner can cite a third document that discloses the general knowledge of the matter and include the bibliographic cite in the technical report as a footnote.

**2.13.6.2 Complementary information and comparative examples**

When facing an objection for lack of inventive step, the applicant can pick one of the following options:

- File arguments or documents to demonstrate that there was a technical prejudice that led a Person skilled in the art in the opposite direction in respect to the invention; or

- Submit evidence, such as comparative trials, to demonstrate the presence of an unexpected technical effect or an advantage of the invention in respect to the closest state of the art. Now then, the trials and data submitted must not be included in the description and, thus, will not be considered an extension to the matter. Also, the results of these trials, by which the applicant intends to demonstrate the inventive step, must be related to the technical effect mentioned in the description at first and not to a different one. For example, if the state of the art describes the preparation of a compound under extreme conditions, the applicant can submit the result of any trial/test that demonstrates that the process claimed can be prepared under less sever conditions. Therefore, the result is evidence that the technical prejudice has been overcome and the procedure claimed is inventive.
- The comparative trials can be requested only if it is absolutely necessary. For example, in the chemical area, comparative trials could be requested if the product claimed and the state of the art are structurally similar and describe the same type of effect (for example, that both are analgesics) or one similar (for example, one is analgesic and the other anesthetic).

**2.13.6.3 Ex post facto or retrospective analysis or hindsight**

It is important to keep in mind that one invention claimed that, at first sight, looks evident can be inventive. Once the new idea is formulated, it is often possible to demonstrate theoretically the way to reach to it, based on something known, through a series of apparently easy stages. The patent examiner must avoid the use of this type of ex post facto analysis.

That is, the state of the art must be examined without considering the knowledge offered retrospectively by the invention claimed. The indication or suggestion to allow reach the invention claimed must originate in the state of the art or the general knowledge of the Person skilled in the art and not in the applicants disclosure.

One of the factors to be considered in order to establish whether the Person skilled in the art as encouraged to combine the documents of the state of the art or not is the reasonable probability of success as a result of such combination of suggestions of the state of the art considered as a whole.

In any case, the patent examiner must struggle to carry out a practical examination according to reality. He/she will consider all that is known regarding the precedents of the invention claimed and give the fair value to the arguments or pertinent evidence filed by the

applicant .

**2.13.7 Inventive step examination for various types of inventions.**

**2.13.7.1 Selection invention**

The selection invention is a Patent that claims one single element or a small group of elements that belong to a wide group of known elements. One selection, for example of a subgroup of products, deemed new, has Inventive Step if all the products of the subgroup show an effect or technical activity not described in the State of the Art and is unexpected, as well.

Therefore, if the examiner can demonstrate that some products claimed do not offer said effect (for example, because they are insoluble, toxic, or unstable compounds, etc.) then it is considered that the entire group of products claimed does not have inventive step. And the applicant should restrict the application to those products that do have that effect or activity.

So the examiner will require the applicant to make a restriction, only based on the documents that demonstrate that some products claimed do not have that effect or activity. The examiner must determine if the matter is patentable and exclude or deny the one that is not, in compliance with the legislation and jurisprudence.

A selection is considered inventive only when the elements selected have an unexpected advantage. And it is denied when such advantage does not exist because it is a common activity to the elements of the wide group.

Obvious selection and, consequently, non-inventive

- The invention consists simply of choosing between a number of probable alternatives; and such selection does not produce a new or unexpected technical effect. For example, choosing the electrical supply of heat in a process is an alternative among some other alternatives known.
- The invention relies on the election of particular dimensions, temperature ranges, or other parameters in a limited range of possibilities; and it is clear that these parameters could have been obtained through a trial and error routine test or the application of common design procedures so that the results obtained are absolutely predictable.
- The invention can be obtained through a simple direct extrapolation from the prior art.
- The invention consists simply of selecting certain chemical compounds or compositions (including combination) in a broad field. And the compounds claimed do not have favorable properties in

comparison with those of the state of the art, or those properties were expected by the moderately Person skilled in the art.

Non obvious selection and, thus, inventive

- The invention involves a special selection in a process of particular operating conditions (for example, temperature and pressure) within a known range; said selection produces unexpected effects in the performance of the process or in the properties of the resulting product.
- The invention consists of the selection of certain chemical compounds or compositions (including combinations) from a broad field where these compounds or compositions have unexpected advantages.

Inventive step in a selection invention in chemistry

A selection invention, for example, the selection of a subgroup of compounds of a Markush formula that is considered new has inventive step if all the compounds of the subgroup present a technical effect or activity not described in the state of the art and, besides, is unexpected.

As a result, if the examiner can demonstrate that some claimed compounds do not show that effect (for example, because the type of substitution makes insoluble or toxic the compound, due to the fact that the compound is unstable, etc.); so, it is considered that the entire group of compounds of the Markush formula does not have inventive step. And the applicant should restrict the application to those compounds that, although new, show activity.

So, the applicant will be required only to make a restriction based on documents demonstrating the compounds claimed that do not have said effect or activity. The examiner must determine the patentable matter and exclude or deny the one that is not, in compliance with the legislation and jurisprudence.

**2.13.7.2 Combination invention**

The combination inventions are those that gather known elements but constitute a new technical solution to a technical problem.

Obvious combination

If the invention claimed is merely an addition, juxtaposition, or association of certain known products or processes that operate with their usual form each, and their technical effects is the addition of them without a functional interrelation between the combined technical characteristics, that is, the invention claimed is just an addition of characteristics, the combination invention does not have inventive step.

But if the combination is just a variation of a known structure, or

it is included in the regular development of the current technology and does not produce an unexpected technical effect, the invention does not have inventive step.

For example, a machine to produce sauces and consists of a known grinding machine and a known filling machine placed one after the other one.

Other example is a machine that consists of two known machines placed one after the other, one to produce donuts and the other to pack them.

Non-obvious combination

If the technical characteristics combined produce a new technical effect, that is, if the technical effect that the combination produces is larger than the sum of the technical effects of the individual characteristics, the invention has inventive step. It is irrelevant if each individual characteristic is totally or partially known.

For example, a mixture of drugs that consists of a specific analgesic and sedative. It is found that the addition of a sedative that are not likely to produce an effect against pain increases the effect of the analgesic, which could not have been expected from the known properties of the active substances.

**2.13.7.3 Transference invention**

The transference invention are those which apply the principles of a known technology in a different technical field. For the inventive step examination, it is important to consider how close the two technical fields to each other are, how difficult the transference is, and the technical effects that result from the transfer of technology from one field to the other.

**2.13.7.4 Invention resulting from the change of elements**

The inventive step examination of an invention that consists of changing elements in known products or processes must consider if there existed a motivation in the state of the art to make said change and if the technical effect produced was expected. These inventions include: inventions resulting from a change of relation between elements, from the replacement of elements, and from the omission of elements.

**2.13.7.4.1 Invention resulting from the change of relation between elements**

These invention are those which form from a change of shape, size, proportion, position, operation relation of a product, or a procedure known in the state of the art.

If the change of relation of elements does not lead to a change of effect, function, or use of the product or procedure, the invention

will be considered non-inventive. For example, if the state of the art discloses a measuring device characterized because it comprises a fixed dial and a rotating needle; and the invention is a similar measuring device characterized because it comprises a rotating dial and a fixed needle, the difference is mainly the change of relation between elements and it does not produce a unexpected effect; therefore, the invention is not considered inventive.

If the change of relation between elements produces an unexpected technical effect the invention must be considered inventive. For example: if the invention is a mower characterized because the crosswise angle of the blade is different to the angle of the mower disclosed in the state of the art;

and the angle of the blade in the invention allows the blade to sharpen automatically, but the angle in the known mower did not allow this effect, the invention is considered to produce an unexpected effect due to the changes of relation between elements; thus, it is inventive.

**2.13.7.4.2 Inventions resulting from the replacement of elements**

An invention of this type consists of replacing an element in a product (mechanical, electrical, or chemical) or in a known process by another elements that is also known; so the invention has the same purpose that is recognized in the state of the art.

If the invention consists of replacing a recently developed material in a known device and the properties of said material make it clearly appropriate for this use and the replacement does not produce an unexpected technical effect, the invention will be considered as not having inventive step.

For example: the invention consists of a pump that differs from the known pump in that it operates using a hydraulic motor instead of an electric one, In this case, the invention does not have inventive step.

**2.13.7.4.3 Inventions resulting from the omission of elements**

These inventions are those that result from removing one or more elements from a known product or process.

If after omitting one or more elements the corresponding function disappears, the invention does not have inventive step. For example: the invention consists of a composition of nail polish that differs from the known composition in that it does not contain a drying agent; as a result, it loses its function as nail polish. In this case, the invention does not have inventive step.

When compared with the state of the art, if after the removal of one or more elements –such as one or more parts of a product or one or more stages in a process– the invention complies with its corresponding

function or produces an unexpected effect, the invention can be considered inventive.

**2.14 Industrial applicability**

The examiner must consider provisions of Art 19 D 486: "An invention shall be regarded as industrially applicable when its subject matter may be produced or used in any type of industry; industry being understood as that involving any productive activity, including services."

By virtue of the foregoing and conforming to article 28 of Decision 486, it is possible that the applicant do not clearly states the industrial applicability of the invention; however, article 28 establishes that said requirement can be fulfilled if the application can be obviously inferred from the description. This obviousness can be perceived from the redaction of the descriptive chapter when the applicant refers to the invention's faculty to be used, or it is easy for a moderately Person skilled in the art to believe that the product or procedure has a substantial industrial applicability.

**2.15 Combined inventions headlined in the form of "Kit of Parts"**

The Kit of parts is a modality of the combined inventions that collects elements which are known individually from independent preparations but can become a new technical solution to the technical problem.

The Kit of parts comprises components that originate from individual preparations where said components form a functional unit (true combination) for a single purpose or technical effect. However, the mere association of components (or simple addition) per se does not make it a functional unit in which the direct interaction called synergy among the components is necessary for the final purpose.

Thus, apply for protection by a patent of a Kit of parts must be considered as an invention eligible for patentability when the core of the invention is a new and inventive combination of two or more known compounds that originate from independent preparations for a specific therapeutic purpose in which the product will be marketed as a Kit of parts.

Having said that, the examiner must study the application using the following approach:

**2.15.1 Determine if the application addresses an invention eligible for patentability**

To differentiate the combination of elements from the simple addition, the examiner must consider that the first constitutes the synergy of

the elements so that a new functional unit with different properties is generated in a way that the unit is the result of said combination, and the elements cannot be determined separately; the second occurs when the elements remain intact regarding their fundamental effect and, thus, can be distinguished from each other, that is, there is not synergy or intrinsic combination of elements.

The examiner must always analyze the instant case and verify the disclosure of the technical effect attributable to the combination or concrete functional unit, due to the fact that cases may arise in which the combination claimed in the form of Kit of parts cannot even be studied, particularly, under the following circumstances:

a) The application is filed as a method. The disclosure comprises a treatment method based on the combined administration of the compounds or functional units in an associated, simultaneous, or sequential manner where each functional unit comprises a series of compounds and from the claims one can conclude that the combination corresponds to a selection of compounds using a first or second list, and characterizes exclusively in terms of a general structure or the function.

b) Change from method claims to Functional Unit. The examiner must not study a change to the claims in this sense when the disclosure of the invention is directed to a therapeutic treatment method or consider the Kit of parts when the invention is characterized in terms of a therapeutic treatment method.

**2.15.2 Patentability substantial examination**

Having considered that the application does not address a treatment method or a matter that cannot be patented, the examiner will have to carry out the content study related with the fulfillment of three requirements: Novelty, Inventive Step, and Industrial applicability, as follows, clarifying that, in respect to the combination or mixture of known elements, a conclusion cannot be obtained a priori because it is not possible to determine instantly the lack of novelty, inventive step, or industrial applicability:

a) Juxtaposition of elements. It occurs when the disclosure mentions concretely the simple addition of one or more active compounds or functional units and, when revising the descriptive chapter the examiner finds that there is no evidence of unexpected effect for the combination. In this case, the examiner can evaluate novelty and inventive step based on what the state of the art discloses and teaches and can conclude that it is the simple addition of elements or the additive interaction of the compounds or functional units, based on

the evidence of its pharmacology function, therapeutic activity, or action mechanism.

b) Synergic combination. When the examiner finds a disclosure in which the claims are directed to a concrete combination of active compounds or functional units, he/she can accept the claims in the form of Kit of parts when they evidence the unexpected technical effect from what was mentioned in the descriptive chapter, and when the documents and arguments submitted by the applicant indicate the unexpected effect.

The examiner can consider that there exists a combination invention when the claim is titled in the form of a Kit of parts, even though the combined elements are not physically connected by a single pharmaceutical delivery system, and it will be enough that a synergic effect or unexpected product derives from the interaction of the preparation as a single functional unit or a true combination; so the examiner will evaluate the effect produced at the moment of the application of the active compounds; nonetheless, no conclusion can be obtained as to it is a therapeutic treatment method .

The combination can be considered new and inventive if there is an unexpected effect; on the contrary, if the effect limits to the sum of the effects produced by compositions A and B, there will be no inventive step because it corresponds to the addition of elements. Although known means may be used, it is possible to accept that there is inventive step to the extent that, when combined for the first time, a different result to that disclosed by each of the known means derives independently or through other combinations.

**2.15.3 Structure of the Kit of parts claims**

The examiner can consider a Kit of parts eligible for a patentability examination when it is characterized by:

- A pharmaceutical preparation or medication A in a defined quantity or proportion; and
- A pharmaceutical preparation or medication B in a defined quantity or proportion.

**2.15.3.1 Evaluation of clarity and conciseness of the combinations included in the Kit of parts claims**

The Kit of parts cannot be defined or characterized in exclusive terms of the intake or administration for, clinical use, metabolism of the drugs combined, or the pharmacokinetic or pharmacodynamics parameters of the combined compounds. In such case, the examiner can formulate an objection for the lack of clarity of the combination claimed.

Neither the Kit of parts can include the preparation instructions nor the administration form of each preparation. In this case, the examiner

will have to carry out the study for lack of clarity to remove the reference to the treatment method and administration of the preparations claimed.

**2.15.3.2 Evaluation of arguments of the combinations included in the Kit of parts claims**

When the examiner notices that the Kit of parts claims include a Markush-type general structure, he/she will issue an objection for lack of clarity and arguments of all the combination inventions derived from choosing a compound of the general structure, combining it with a second compound, and including it in the preparations or functional units. And the examiner will revise the disclosure of the unexpected effect for the series of combinations claimed in the Kit of parts form.

**2.15.4 Examples of Kit of parts claims eligible for study**

**2.15.4.1 Example of a combination invention of pharmaceutical compounds claimed in the form of Kit of parts with a proved synergic effect.**

The technical problem disclosed in the application consists of reducing the collateral effects caused by the anti-tumor therapy in patients that suffer from breast cancer when the gemcitabine and carboplatin therapy is applied.

The solution to the technical problem consists of applying compound 4-iodo-3-nitrobenzamide in combination with gemcitabine and carboplatin in a reduced dose regime that gives the benefit of a better survival profile while inhibiting the progression of the disease (PFS) in patients in comparison with the gemcitabine/carboplatin therapy .

In the present case, the results of the tests performed in a group of patients –according to the pharmacotherapy follow-up and the evaluation of the progression of the disease– are shown based on the occurrence of the adverse effects that result from the application of the gemcitabine/carboplatin therapy in respect to the 4-iodo-3-nitrobenzamide/gemcitabine/ carboplatin therapy.

Claims:

Claim 1: a Kit of parts that comprises a combination of vials where the first vial comprises the 4-iodo-3-nitrobenzamide or a pharmaceutically acceptable salt of the same, the second vial comprises gemcitabine, and the third comprises carboplatin.

Claim 2: the kit of claim 1, where the measured-out quantity of 4-iodo-3-nitrobenzamide or a pharmaceutically acceptable salt of the same is 3 to 20 mg.

Claim 3: the kit of claim 1, where the measured-out quantity of gemcitabine is 18 to 16.050 mg.

Claim 4: the kit of claim 1, where the measured-out quantity of carboplatin is 1.8 to 1.284 mg.

Evaluation of the State of the Art (SoA):

Based on the search of the nearest SoA, document XP002633901 was found, which was published in 2004 and evaluates the advantages of applying the combination of gemcitabine/carboplatin as a second-line treatment to combat breast cancer. However, the document does not suggest or disclose the possibility to include a third anti-cancer agent of the benzamide type or a reduction in the dose to achieve an anti-tumor effect and a higher level of survival inhibiting the progression of the disease; therefore, when faced with the absence of a nearest SoA that would suggest or motivate the Person skilled in the art to combine the three anti-tumor agents and facing the evidence of an unexpected technical effect, it was concluded that the matter claimed complies with the novelty, inventive step and industrial applicability requirements to the extent that the combination will be marketed in the form of a Kit of parts that includes three vials or functional units.

**2.15.4.2 Example of a combination invention of bio-pharmaceutical compounds claimed in the form of Kit of parts with a proved synergic effect.**

The technical problem disclosed in the application consists of designing an alternative anti-tumor combination therapy that is selective only before tumor cells.

To solve this technical problem the application shows a combination of agents; the first bioactive agent is produced by Basidiomycete fungi (oligosaccharide, polysaccharide, fatty acid, or a glycosylated polypeptide); and the second, an anti-cancer synthetic agent such as Docetaxel that, when being applied both combined, show more selectivity above a colon cancer cellular line measured in terms of cytotoxicity, in accordance with the MTT test (activity of mitochondrial succinate dehydrogenase) .

Claims:

Claim 1: a pharmaceutical Kit of parts that comprises (a) an anti-cancer medication such as Docetaxel; (b) a bioactive agent obtained from Basidiomycete in a solid-liquid form.

Claim 2: the kit of claim 1, where the bioactive agent of Basidiomycete is selected from the group that consists of an oligosaccharide, a polysaccharide, and a fatty acid .

Claim 3: the kit of claim 2 can comprise two or more types of administration preparations (nasal, aerosol, subcutaneous, parenteral,

oral, topic) but the same route of administration of all the elements in the kit is preferred.

Evaluation of the state of the art (SoA):

The first component is a known anti-cancer compound; however, according to the evaluation of the SoA and the nearest documents, particularly document XP002402437, both active compounds had never been combined neither to provide a joint anti-cancer effect nor to form a composition; also, the selective cytotoxic activity of the bioactive compounds obtained from the Basidiomycete fungi had never been evaluated; so, when faced with the absence of a near SoA that would suggest or motivate the Person skilled in the art to combine both anti-tumor agents, and facing the evidence of an unexpected technical effect associated to the selectivity over the colon cancer cells, it was concluded that the matter claimed fulfills the novelty, inventive step, and industrial applicability requirements to the extent that the combination will be marketed in the form of a Kit of parts that includes two functional units.

Thus, the Kit of partss containing active components from independent preparations are applied preferably at the same time and through the same route, in accordance with the disclosure of the invention.

The combination claimed is not the simple addition of known agents but a combination invention titled as Kit of partss that has the unexpected property of achieving improved anti-cancer effects.

**2.15.4.3 Example of a Kit of parts that correspond to the juxtaposition or simple addition of compounds with a known pharmacologic activity**

The technical problem disclosed in the application consists of improving the efficacy of the anti-tumor therapy through the design of a pharmacotherapy alternative. To solve this technical problem the application shows a combination of anti-tumor agents; the first a chemosensitivity inhibitor of the polymerase enzyme (ADP-ribose) derived from azepine which is capable of increasing the pharmacologic efficacy of other cytotoxic agents .

The technical tests are aimed at demonstrating the chemosensitivity effect derived from azepine when the patient is subject to radiotherapy.

Claims:

Claim 12. Kit to treat cancer in mammals, which comprises:

(a) An amount of compound of formula 1 that corresponds to the compound 8-fluoro-2-{4-[(methylamine)methyl]fenyl}-1,3,4,5-tethrahydro-6H-azepine[5,4,3-cd]indol-6-ona and a vehicle pharmaceutically acceptable in a first preparation form and unitary dosage.

(b) An amount of at least one anti-cancer agent and a pharmaceutically

acceptable vehicle in at least one second preparation form and unitary dosage.
(c) Container to hold the first and, at least, the second dosage forms.
The Kit of parts claimed does not comply with the condition of being new, inventive, and have an industrial applicability because the state of the art contains documents that disclose combinations or compositions of the formula 1 compound with other anti-cancer agents of diverse nature and origin, particularly in the state of the art document WO0042040; and, on the other hand, there is no technical evidence of a true combination of compounds or functional units because the technical tests are aimed at demonstrating the chemosensitivity effect caused by the azepine when administered to a patient that will be subject to radiotherapy.

**2.15.5 Example of Kit of parts that correspond to a therapeutic treatment method**

The technical problem consists of reducing the incidence of male subfertility as a consequence of failures in the prostatic function. To solve this problem, the investigators found that high levels of interleukin (IL) 8 in seminal plasma are correlated with the seminal parameters of sub-fertile individuals; as a result, they design a treatment method and Kit of parts based on the diagnosis of IL 8 and the administration of vitamin D .
Clinical trials are aimed at determining the effect of vitamin D on seminal parameters such as the morphology of sperms, mobility, leukocyte levels in the semen, and the conception rates of patients submitted to treatment.

Claims:
Claim 1: A method to treat male subfertility, which consists of applying vitamin D.
Claim 2: A treatment method that consists of the route of administration of vitamin D with the instructions and quantity in the dosage form to be administered over a determined time and the container, recipient, or package.
Claim 3: the method in claim 2 characterized because it also comprises the identification of the patient that needs the male subfertility treatment.
Claim 4: the method of claims 2 or 3 characterized because it also comprises the steps to obtain the vitamin D compound.
Claim 5: the method of claims 2 to 4 where the patient is a mammal and is a human being.

Claim 6: the Kit of parts that comprises: i) the determination of the interleukin levels (IL) 8 in seminal plasma, ii) the administration of vitamin D, and iii) the administration guidelines.
The object disclosed by the application relates with a treatment method, and one of the claims mentions a Kit of parts that contains the compounds administered to a patient plus a test to diagnose the IL-8 levels. In this case, it is understood that the Kit of parts is a diagnosis and treatment method; therefore, it is not patentable under article 20 literal d) D 486 and, as a result is not eligible for the patentability examination.

**2.15.6 Evaluation of unity of invention in the claims titled as Kit of parts and the disclosure of the unexpected effect.**

The examiner can evaluate the lack of unity of invention for a series of Kit of parts claims when faced with the absence of a common and inventive concept that would comprise a group of invention combinations and when the disclosure shows no evidence of an unexpected effect for all the combinations defined in the claims.
The inventive common concept of a Kit of parts is the concrete, new, and inventive combination of the specific components included in the preparations, defined by their names each, and for which there is evidence, in the disclosure, of an unexpected effect, as a consequence of its combined application.
The examiner, when faced with a Kit of parts claim that includes a Markush-type general structure from which a component to be included in the combination will be chosen, must revise the unexpected effect evidence disclosed in the application for the entire group of combination inventions derived from the general structure and, where appropriate, formulate an objection for insufficient disclosure of the unexpected effect.
And when the examiner finds that there is not a structural-type inventive common concept for each concrete combination, he/she will issue an objection for the lack of unity of invention with the purpose of studying the different inventive groups provided in the requirement or those filed by the applicant, and study the corresponding divided applications.

# 3 CHAPTER III. CHEMISTRY AND PHARMACEUTICS

## 3.1 Novelty

If a document in the state of the art is clearly defined by its chemical name or the molecular or structural formula, the physical/chemical parameters, or the manufacturing process, a compound claimed in the application, the examiner will conclude that the compound lacks novelty.

For example: if the chemical name and the molecular or structural formula of a compound disclosed in a document of the state of the art is not clear to identify the compound, but the document discloses the same parameters of the compound claimed, it can be deducted that the compound claim lacks of novelty unless the applicant is able to demonstrate that the compound was not available before the filing or priority date.

If a product corresponds in all its aspects to another of the state of the art (for example, the initial products and the manufacturing process are identical), but the state of the art does not mention a particular parameter defined in the claim, an objection must be stated at first due to a lack of novelty by saying that the state of the art would probably have the same value for said parameter if measured. This will apply especially if the parameter is unusual or unknown.

If the applicant demonstrate that the parameter is really different in the invention claimed in respect to the state of the art, for instance, using valid arguments or comparative trials, it will be considered new. If the chemical name and the molecular or structural formula of a compound disclosed in a document of the state of the art is not clear enough to identify the compound, but the document discloses the same preparation method as that of the compound claimed in an application, the compound lacks novelty.

A general formula cannot destroy novelty of a specific compound included in the general formula. However, the disclosure of a specific compound destroys novelty of a general formula claimed that contains said specific compound but does not affect the novelty of a different specific compound contained in said general formula. A series of specific compounds in the series can destroy the novelty of the corresponding compounds in the series.

Compounds in a range such as C1-4 annul novelty of the specific compounds of the maximum ranges (C1 and C4). However, if the compound C4 has many isomers, compound C1-4 does not make each isomer lose novelty.

When both the claim and the document in the state of the art are defined by Markush formulas that overlap, that is, there exists a subgroup of compounds that are common to both, but the state of the art does not describe a concrete compound in this subgroup, it is pertinent to allege the lack of novelty explaining that the compounds claim are partially in the state of the art, and no new effect in the overlap field is detected.

A natural product does not destroy novelty of a product invention only if the natural product has been disclosed and is identical or has an equivalent structure and morphology to the invention of product.

**3.1.1 Novelty of a composition defined by its components**

If the object of an application consists of a composition Y that contains the components A+B, then it is compared with a composition of the state of the art X that contains A+B+C, the examiner will conclude that the claim is not new.

On the other hand, if the object of an application consists of a composition Y that contains the components A+B+C, it is compared with a composition of the state of the art X that contains A+B, the examiner must conclude that the claim is new.

**3.1.2 Novelty of a chemical product characterized for its parameters of manufacturing process.**

- If for the examiner it is impossible to compare a chemical product characterized by its parameters, with the product disclosed in the state of the art, he/she will deduct that the product claimed by said parameters is not new.
- If a claim refers to a chemical product characterized for its manufacturing process, the examiner will have to determine the novelty of the product per se and not through comparing between the manufacturing process and the process disclosed in the state of the art because a different process not always produce a different product. If the product of the invention compared with the product disclosed in the state of the art is found to have only a different manufacturing process and no parameters exist to differentiate them or there is not a change in the functions or resulting effects from the differences in the processes, then it is deducted that the claim of the product defined by the process lacks novelty.

**3.2 Inventive step**

The inventive step examination must be carried out using the problem-solution approach as follows:

- Identify the closest state of the art to the invention

- Determine the difference between the invention claimed and the closest state of the art
- Define the technical effect produced by including said difference
- Define the objective technical problem
- Define if the selection is inventive. If the answer to these questions is affirmative: (a) would a moderately Person skilled in the art recognize the problem? (b) Would this person solve it in the form claimed, based on the state of the art, without making an inventive effort?; then, it can be concluded that the selection claimed is obvious.

A selection, for example of a product subgroup, considered new, will have inventive step if all the products of the subgroup show a technical activity or effect that is not described in the state of the art and, thus, is unexpected.

Therefore, if the examiner can demonstrate that some products claimed do not present said effect (for example, because they as insoluble, toxic, or unstable compounds, etc.), then, the entire group of products claimed are considered to lack inventive step. And the applicant should restrict the application to those products that do have that effect or activity.

So, the applicant will be required to make a restriction based only on documents that demonstrate that the products claimed do not have said effect or activity; the examiner must determine the patentable matter and exclude or deny the one that is not in accordance with the state of the art and conforming to the legislation and jurisprudence.

A selection is considered inventive only when the elements selected have an unforeseen advantage. And it is denied when said advantage does not exist; conversely, it is a common activity to the broad group elements.

**3.2.1 Obvious selection and, thus, not inventive**

- The invention consists simply of selecting among a number of similarly probable alternatives.
- The invention relies on the election of particular dimension, temperature ranges or other parameters with a limited range of possibilities; and it is clear that those parameters could have been obtained through a trial and error routine or the application of common design procedures, so that the results obtained are absolutely predictable.
- The invention can be carried out through a simple direct extrapolation from the prior art.
- The invention consists of just selecting certain chemical compounds

or compositions (including the combinations) within a broad field. And the compounds claimed do not have advantageous properties in respect with those of the state of the art, or said properties were expected by a moderately Person skilled in the art.

**3.2.2 Non-obvious selection and, thus, inventive**

- The invention involves a special selection in a process of particular operation conditions (for example, temperature and pressure) within a known range; said selection produces unexpected effects in the process performance or the properties of the resulting product.
- The invention consists of the selection of certain chemical compounds or compositions (including the combinations) from a broad field, where those compounds or compositions have unexpected advantages.

In a selection invention, for example of a subgroup of Markush-formula compounds that is considered new, this invention will have inventive step if all the compounds of the subgroup show a technical effect or activity not described in the state of the art and is unexpected, too. Hence, if the examiner can demonstrate that some of the compounds claimed do not show that effect (for example, because the type of substitutient makes the compound insoluble or toxic, because the compound is unstable, etc.), then the whole group of compounds of the Markush formula is considered not to have inventive step. And the applicant should restrict the application to those compounds that are new and have activity.

So, the applicant will be required to make a restriction based only on documents that demonstrate that the compounds claimed do not have said effect or activity; the examiner must determine the patentable matter and exclude or deny the one that is not in accordance with the state of the art and conforming to the legislation and jurisprudence.

**3.2.3 Later strategy**

The examiner can suggest the applicant to restrict the application to the inventive compounds if, in view of the inventive step examination, it can be demonstrated that some of the compounds claimed do not show an unexpected effect.

If the applicant ignores the restriction requirement, the objection will be ratified. If the applicant still ignores the examiner’s suggestion to restrict the claim to the invention compounds of the application, it will be considered that the compounds of the selection are not inventive and the application will be denied. Otherwise, the application will be awarded.

On the other hand, if the applicant files comparative data, this information will be accepted as experimental evidence that the

compounds of the selection have advantages in respect to those known in the state of the art.

**3.2.4 Compounds**

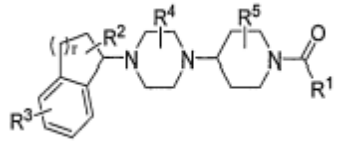
- When a compound is new because its structure is not similar to that of a known compound, and it has a certain use or effect, the examiner can consider that it has inventive step, without requiring the effect to be unexpected.
- If a compound has a similar structure to that of a known compound and its effect is unexpected, it will be considered inventive. For example, if the compound claimed A is an antibiotic and has a similar structure to compound B of the state of the art that is an antidepressant, it can be deducted that compound A has inventive step because it shows an unexpected effect.
- If a compound has a similar structure to that of a known compound but its effect is not unexpected, it will not be considered inventive.
- The examiner must explain why he/she considers that the effect shown by a new compound, which structure is similar to the structure of a known compound, is obvious or predictable for a Person skilled in the art and, consequently, does not have inventive step.
- If the effect obtained by the invention is caused as a result of a known or inevitable reason, the technical solution does not have inventive step. For example, the insecticide A-R, where R= alkyl C1-3, is already known and the state of the art states that the insecticide effect is improved when the number of atoms in the alkyl is increased. If the invention claimed is an insecticide A-C4H9, it is obvious that its insecticide effect will be stronger. Therefore, the invention claimed lacks inventive step.

**3.3 Markush Formula**

**3.3.1 What is a patent application that includes Markush formulas?**

It is a type of application that comprises various alternatives of the invention in a single claim. The necessary condition for the alternatives is that they are of similar nature; that is, they have a common activity and structure. This type of patents happen in the chemical and mechanic fields.

Example: the claim refers to formula compounds(ommit)



In which:
R1 is heteroaryl substituted by one or more R6,
R2 is H, phenyl, sulfonamide, alkyl C1-6, F, Cl, Br, I, halo alkylC1-4, halo alcoxyC1-4, heteroaryl,
R3 is F, Cl, Br, I, halo alqkylC1-4, halo alcoxyC1-4, heteroaryl,
R4 is H, alkylC1-6, alkenylC2-6, alkynylC2-6, halo alkylC1-6, and
R5 is H, alkylC1-6, alkenylC2-6, alkynylC2-6, halo alkylC1-6

**3.3.2 Patentability examination**

The examination of a Markush-type patent application is performed following the conventional order; that is, first the novelty and next the inventive step.

**3.3.3 Description examination**

**3.3.3.1 Clarity**

The description is considered clear if the information it contains allows a Person skilled in the art to understand the technical problem and the solution provided by the invention.

**3.3.3.2 Sufficiency**

Moreover, it is considered that the description discloses the invention sufficiently complete for a Person skilled in the art to carry out (or reproduce) the alternatives of the invention without having to make an inventive effort beyond his/her ordinary skills. Therefore, if the description omits information that is necessary to carry out the invention and cannot be replaced by the general knowledge of a Person skilled in the art, the invention will be considered not to be sufficiently described.

Now then, if the description comprises a very large number of alternatives (variations, variables, options, permutations/exchanges, or carry-out modes), and its excessive complexity makes it difficult for a Person skilled in the art to reproduce all the types of products described, it will be considered that it does not fulfill the sufficiency requirement.

**3.3.4 Examination of claims**

**3.3.4.1 Conciseness**

If a Markush-type claim comprises a very large number of alternatives and, thus, is not concise and its excessive complexity makes it difficult to determine the scope of the object that is seeking protection, a requirement will be issued suggesting the applicant to restrict the application to a reasonable generalization of the type of compounds that has been synthesized or proved; the intention is not to restrict to the examples alone.

**3.3.4.2 Support**

If a Markush-type claim comprises a very large number of alternatives but only a small number of them is supported in the description, a requirement will be issued suggesting the applicant to restrict the scope of the application to a reasonable generalization of the type of compounds that has been synthesized or proved.

**3.3.4.3 Unity of invention**

The so-called "Markush Practice" is a structure that comprises various alternatives of the invention in a single claim. The necessary condition for the alternatives is that they are of similar nature, that is, they have a common structure and activity.

Before formulating an objection for unity of invention, the examiner must verify if there exists a single inventive concept. The common inventive concept of a group of compounds is its common structure and property.

There will be unit of invention under the following situations:

**3.3.4.4 Undefined compounds**

There will be no unity of invention if the compounds are not defined by a chemically defined central structure; on the contrary, its structure is of the type A-B-C-D.

**3.3.4.5 All the variations are of similar nature**

That is, there is unity of invention when all the variations have a common chemical structure and one common property or activity. And the common chemical structure takes a great part of its structures or is part of its structure that in the view of the state of the art is distinctive (from the structural point of view) and essential (for the common property or activity).

In the field of the pharmaceutical compounds, the common chemical structure provided by the common activity or property is called "pharmacophore". So, a group of compounds that share the same pharmacophore group distinctive at the sight of the state of the art (because is new and inventive) has unit of invention.

Also, if the different variations of the compounds claimed are distinctive isosteres or bio-isosteres, it is considered that there is unity of invention among them.

**3.3.4.6 The compounds belong to a class of known chemical compounds**

There is unit of invention if all the variations have a specific common property or activity and in the cases in which the structure is not common, all the variations belong to a type of chemical compounds that is recognized in the technical sector.

"Known class of chemical compounds" means that, in the view of the

state of the art, the members of said class are expected to behave in the same way. That is, all the alternatives have a common property or activity so each member can substitute the other with the expectation to achieve the same foreseen result.

**3.3.4.7 Intermediate products and final products**

The examiner will remember that there is unit of invention between intermediate and final products when:

- The intermediate and 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 intermediate that share the same essential structural element.

Whenever they have the same essential structural element or the intermediate includes an essential element in the final product, the examiner will bear in mind that there is unity between;

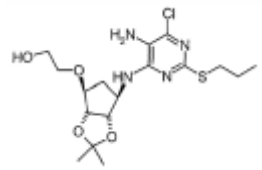
- A new intermediate and a new final product;
- A known intermediate and a new final product;
- Different intermediate of different procedures to obtain the final product;
- An intermediate and a final product of a process that directs from one to the other, or by a known intermediate; or
- The intermediate and final products that are families of compounds and each intermediate corresponds to one of the final products.

No unity will exist if:

The intermediate and final products are families of compounds and any of the final products do not correspond in the family of the intermediate. It will be considered that there is not unity between different intermediate for different structural zones of the final product.

Example (WO0192263):

Given that Compound (I):

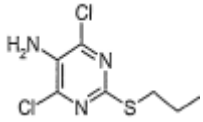



which is the final product, is

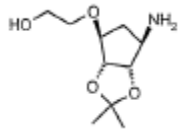
known (in WO9941254), it is considered that there is not unity between

the two intermediates:

Compound (II):



and Compound (III):



which conform structural zones that are different from the final product.

If the examiner recognizes, through the application of the prior interpretations, that there is unity of invention, the fact that the intermediates, in addition to their use to obtain the final products, show other effects or activities will not affect the decision about the unity of invention

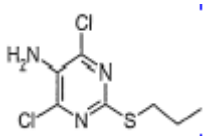
**3.3.4.8 Examples to determine the unity of invention**

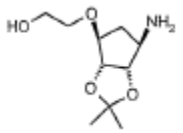
**3.3.4.9 Example 1 of unity of invention**

"Derivatives of Quinuclidine common to muscarinic M3 receivers"

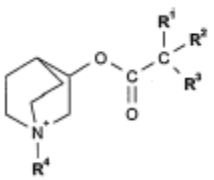
Method to examine the unity of invention

Content of the application, "Derivatives of Quinuclidine common to muscarinic M3 receivers" (WO2004/096800):





The application relates with derivatives of formula (I) quinuclidine:



Characterized by

An acetoxy group substituted in position 3;
An R4 group over the Nitrogen, substituted by an alkyl group C1-C8, amine, ester, or ether; or
An alkynyl C3-C10 group
The compounds disclosed are common to the human muscarinic M3 acetyl choline receiver and are useful for the treatment of diseases mediated by those M3 such as the allergic inflammation.
Identify the invention mentioned at first and identify its essential technical characteristics. And identify all the other possible inventions and their essential technical characteristics.
Apparently, there is no common structural element or a particular pharmaceutical activity that contributes to the state of the art and, thus, represent a single inventive concept.
According to the foregoing, 4 inventive groups have been identified:
- Formula (I) compounds characterized by a radical R4 substituted by an amine with a NHR5 formula.
- Formula (I) compounds characterized by a radical R4 substituted by an acidic derivative of formula –NR5COR6–, –NR5CONHR7–, –NR5SO2R8–, –CONR9R10–, –OCONHR12–, –OCOR13–, –COOR14.
- Formula (I) compounds characterized by a radical R4 substituted by a formula OR11 ether. And
- Formula (I) compounds characterized by a radical R4 that is a C3-C10 alkynyl.
Do a search and examine novelty and inventive step using the problem-solution approach to every possible invention.
D1 discloses derivative of quinuclidine with activity over the muscarinic acetyl choline M3 receiver characterize by a residual –(CH2)m–A–(CH2)n–phenyl over the Nitrogen atom of the quinuclidine where A is defined, among other, as –O–, –CO–, and –NR6–. For the definition “n” is 0, among other (see examples 1, 2, 33, 133, and 135), D1 discloses derivatives of quinuclidine with an amine or ether function.
Novelty:
The object of groups 1, 2, 3, and 4 differs from the state of the art; therefore, the groups are new.
Inventive step:
D1 is considered the closest state of the art. It discloses derivative of quinuclidine which is highly common to the M3 receivers and are useful to treat respiratory diseases.
Examination of the first possible invention:
The solution consists of formula (I) compounds characterized by a

radical R4 substituted by an amine with formula NHR5 where R5 represents Hydrogen or alkylC1-C8.
D1 is considered the closest state of the art. It discloses the quinuclidine derivatives that are highly common to the M3 receivers and are useful for the treatment of respiratory diseases.
There is no evidence of the technical effect achieved by the inclusion of the new substitutients because there is no data in this sense.
The objective technical problem can be considered as the need to provide alternative derivative compounds of the quinuclidine.
D2 discloses a wide variety of residuals over the Nitrogen of the quinuclidine; and D1 also mentions them in example 133.
So, including an alkylC1-C8 instead of a phenyl is considered just one of various possibilities that a Person skilled in the art would choose, without performing any inventive activity to solve the problem.
Thus, it is considered that the compounds of Group 1 do not have inventive step.
Examination of the second possible invention:
The solution consists of formula (I) compounds characterized by a radical R4 substituted by an acidic derivative with formula –NR5COR6–, –NR5CONHR7–, –NR5SO2R8–, –CONR9R10–, –OCONHR12–, –OCOR13–, –COOR14.
D1 is considered the closest state of the art because it discloses derivatives of quinuclidine that are highly common to the M3 receiver and are useful for the treatment of respiratory diseases.
The effect achieved is the high relation to the M3 human receiver contained in the compounds claimed because examples 17, 34, 52, and 76, which have a phenyl-amide substitutient, show Ki values in the test (page 9) lower than 1 µM (0.014, 0.002, 0.002 y 0.001 respectively).
The objective technical problem is the need to provide derivatives of quinuclidine that are highly common to the human M3 receiver.
On the other hand, D5 discloses ester residuals in the corresponding position of quinuclidine. And D1 discloses various types of A substitutes over the Nitrogen of the quinuclidine; this indicates the Person skilled in the art that the activity of these compounds over the M3 receiver has certain tolerance in respect to R4 variations.
Therefore, the solution to the problem is obvious for the Person skilled in the art who expected to obtain opponents to the M3 receiver, knowing the pharmacologic effect that the radicals disclosed in D5 would provide to the quinuclidine molecule in D1. Then, it is considered obvious.
In view of the foregoing, it is considered that the compounds of Group

2 do not have inventive step.
Examination of the third possible invention:
The solution consists of formula (I) compounds characterized by a radical R4 substituted by an ether with formula OR11.
D1 is considered the closest state of the art because it discloses derivatives of quinuclidine that are highly common to the M3 receiver and are useful for the treatment of respiratory diseases.
The difference between the invention and the compounds in D1 consists of the radical R4 substituted by an ether with formula OR11 where R11 is an open chain.
There is no evidence of the technical effect achieved with the inclusion of an ether with formula OR11 where R11 is an open chain because there is no data to confirm that.
Therefore, the Objective Technical Problem that this invention intends to solve can be stated as follows: "how to modify the known compounds in D1 to achieve the alternative quinuclidine derivative compounds."
However, D3 discloses a great variety of substitutes over the Nitrogen of the quinuclidine.
Consequently, a knowledgeable person in the matter would include an R11 group, which is an open chain, instead of the phenyl ring to the derivatives of quinuclidine included in D1, in accordance to the guidelines of D3 to achieve the object of the invention under study. Thus, it is considered obvious.
Then, the compounds of Group 3 are considered that they do not have inventive step.
Examination of the fourth possible invention:
The solution consists of formula (I) compounds characterized by a radical R4 that is an alkynyl C3-C10. D1 is considered the closest state of the art because it discloses derivatives of quinuclidine that are highly common to the M3 receiver and are useful for the treatment of respiratory diseases.
The difference between the invention and the compounds in D1 consists of the radical R4 that is an alkynyl C3-C10.
The effect achieved is that it is highly common to the M3 human receiver with the same compounds claimed because examples 54 and 114, which have an alkynyl substitute, show Ki values in the test (page 9) that are lower than 1 µM (0.0001 y 0.0002 respectively).
The objective technical problem is the need to provide derivatives of quinuclidine that are highly common to the human M3 receiver.
On the other hand, D2 already disclosed that the alkynyl group (group "A" in D2) in the quinuclidine derivatives allowed the affinity with

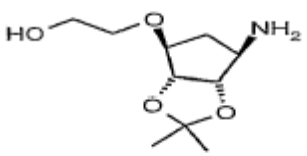
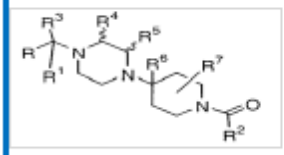
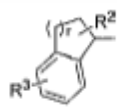
M3 receivers, which indicates the Person skilled in the art that it is included in this type of compounds.
Thus, the solution to the problem is obvious for the Person skilled in the art who would expect to obtain opponents to the M3 receiver by knowing the pharmacologic effect provided by the radicals disclosed in D2 to the quinuclidine molecule of D1. Hence, it is considered obvious.
In view of the foregoing, the compounds of Group 4 are considered not to have inventive step.
Compare the objective technical problem and the essential technical characteristics of each possible invention.
The lack of unity of invention would be explained as follows:
There are no common technical elements to the four inventions claimed because the distinctive technical elements of each invention are not identical.
Since there is no relation between the technical elements of the different inventions, there is not a single inventive general concept.
Consequently the requirement of Art. 25 D 486 is not fulfilled.

As a result, the claims would be grouped as follows:
First invention: formula (I) compounds characterized by a radical R4 substituted by a formula NHR5 amine.
Second invention: formula (I) compounds characterized by a radical R4 substituted by an acidic derivative with formula –NR5COR6–, –NR5CONHR7–, –NR5SO2R8–, –CONR9R10–, –OCONHR12–, –OCOR13–, –COOR14.
Third invention: formula (I) compounds characterized by a radical R4 substituted by a formula OR11 ether.
Fourth invention: formula (I) compounds characterized by a radical R4 that is an alkynyl C3-C10.

**3.3.5 Novelty examination**

The novelty examination must be performed as follows:
- Identify and list the essential technical characteristics of the Markush structure of the independent claim.
- Identify the technical characteristics of the structure in the documents of the state of the art.
-Compare the essential technical characteristics with those of the state of the art using a matrix similar to the one shown below:

Comparison of the essential technical characteristics with those in the state of the art

| Essential characteristics | D1 |
|---|---|
| Formula compounds:<br>  | Formula compounds:<br>  |
|  |  <br>**R** |
| | **Phenyl** |
| | **Naphthyl** |
| | **R1cyclopenthane** |
| | **R3phenyl** |
| $R^1$ | $R^2$ |
| heteroaryl substituted by 1 or more $R^6$ | heteroaryl (6 members) substituted by $R^9$, $R^{10}$, or $R^{11}$ |
| $R^2$ | Not mentioned |
| H | Not mentioned |
| Phenyl | Not mentioned |
| Sulphonamide | Not mentioned |
| alkyl$C_{1-6}$ | $R^{18}$ |
| F | F |
| Cl | Cl |
| Br | Br |
| I | I |
| halo alkyl$C_{1-4}$ | -$CF_3$ |
| halo alcoxy$C_{1-4}$ | $CF_3O$- |
| Heteroaryl | Heteroaryl |
| **$R^4$** | **$R^4$** **$R^5$** |
| **H** | **H** **H** |
| **alkylC1-6** | **alkylC1-6alkylC1-6** |
| **alkenylC2-6** | **Not mentioned** |
| **alkynylC2-6** | **Not mentioned** |

| Essential characteristics | D1 |
|---|---|
| halo alkylC1-6 | Not mentioned |
| $R^5$ | $R^7$ |
| H | H |
| alkylC1-6 | alkylC1-6 |
| alkenylC2-6 | Not mentioned |
| alkynylC2-6 | Not mentioned |
| halo alkylC1-6 | Not mentioned |

- The examiner must render technical concept to communicate the applicant that some structures in the claim overlap with structures in the state of the art and, thus, are not new; the examiner will make the comparative study and show the results in a table, as well as conclude that the independent claim under examination is not new.
- Now then, if the state of the art reveals a specific compound that, according to its structure, is included in the Markush formula claimed, said compound is not new. And given that "what is particular in the state of the art annuls the novelty of what is general in the claim", it will be considered that all the group of compounds in the Markush formula claimed is not new. And a technical concept will be rendered concluding that the independent claim under examination is not new.
- The examiner can suggest the applicant to restrict the application to the new compounds, with the purpose of examining the inventive step of the group of new compounds in the Markush formula.
- If the applicant ignores this restriction requirement, the objection will be ratified. If the applicant still ignores the requirement to restrict the claim to the new compounds of the application, the whole group of compounds in the Markush formula will be deemed not new and the application will be denied.

**3.3.6 Inventive step examination**

The inventive step examination of the Markush-type application will be done using the problem-solution approach as follows:

- Identify the closest state of the art to the invention.

The closest state of the art to the Markush formula claimed will be the document that discloses the same type of compounds and mentions the larger number of common technical characteristics to the Markush formula claimed, and its technical purpose is similar or equal.

- Determine the difference between the invention claimed and the closest state of the art.

The same way as it was determined for the novelty examination

Define the technical effect caused by the difference and that is

attributable to said difference.
The technical effect can be defined if the description mentions the result of any activity test performed; but some applications might not mention a technical effect or there might not be evidence of the technical effect at all.
- What is the objective technical problem?
The examiner must deduct the objective technical problem in the light of the closest state of the art and based on the technical effect provided by the Markush formula claimed. Thus, the objective technical problem can be different from the subjective technical problem filed by the applicant at first.
The objective technical problem can be formulated like this: "how to modify the closest state of the art to achieve the technical effect provided by the compounds of the Markush formula claimed."
If there is no evidence of a technical effect, the objective technical problem will be considered as "the need to provide alternative compounds of… (Known compounds)".
- Determine if the Markush formula is inventive
If the answer to these questions is affirmative (a) would a Person skilled in the art recognize the problem? (b) Would this person solve it in the form claimed, based on the state of the art, without making an inventive effort? Then, it can be concluded that the Markush formula claimed is obvious and, as a result, not inventive.
Now then, if the examiner has defined the technical problem as "the need to provide alternative compounds of…" which produces the same or similar effect, he/she can conclude that the closest state of the art described the solution; therefore, the compounds claimed are not inventive.
An invention of a subgroup of compounds of a Markush formula that is considered new has inventive step if all the compounds of the subgroup show a technical activity or effect not described in the state of the art and is unexpected, too.
Therefore, if the examiner can demonstrate that some compounds claimed do not show that effect (for example, because they are insoluble, toxic, unstable compounds) then it is considered that the entire group of products claimed do not have inventive step. And the examiner can suggest the applicant to restrict the application of the inventive compounds, that is, those that do have said effect or activity.
So the applicant will be required to make a restriction only based on the documents that show the claim products that do not have that effect or activity.

A Markush-type selection application is considered inventive only if the compounds claimed show a different, increased, or improved activity in comparison with the compounds in the state of the art, and that activity is due to the modification introduced in the chemical structure or solve unexpectedly the objective technical problem.
If the applicant ignores this restriction requirement, the objection will be ratified. If the applicant still ignores the requirement to restrict the claim to the inventive compounds of the application, the whole group of compounds in the Markush formula will be deemed not inventive and the application will be denied.
If the applicant submits comparative data, this information will be accepted as experimental evidence that the compounds have advantages in respect to the compounds known in the state of the art.
On the other hand, if the applicant increases the number of compounds mentioned in the claims, the extension of matter filed at first will be objected.
If the examiner concludes that the Markush formula of the application is new and inventive, the composition and the procedure to prepare them will be considered new and inventive as well.

### 3.4 POLYMORPHOUS

#### 3.4.1 What is polymorphism?

In general, the solid substances have a crystalline and amorphous shape (without crystalline order); in the first case, they can be described, among other, for their external appearance called crystalline habitus or for their internal structure. Polymorphism is the capacity of a substance to exist in two or more crystalline phases presenting different arrangements and/or conformation of molecules in the crystal in each phase. Thus, the various polymorphous of a substance show the same chemical composition but differ in their crystalline structure which confers them different physical chemical properties in their density, hardness, hygroscopic tendency, dissolution rate, thermal stability, or behavior when suspended. However, it is worth mentioning that the polymorphous show the same properties in liquid or gas state.
Most of the active chemical compounds, either of pharmaceutical or agricultural use, show transformation of phases that materialize in:
- A new crystalline order of the compound or its salts, said order being called polymorphic, and/or
- A molecular adduct formed between the compound and the solvent called pseudopolymorphic. When the compound incorporates water molecules

(solvent) in its structure, the resulting compound is known as a crystalline hydrate; and in the case the adduct forms with other type of solvent, the resulting compound is called crystalline solvate.

**3.4.2 Examination of the description and the claims**

The main criteria considered in the patentability examination of a polymorphous are:

**3.4.3 Examination of the description**

**3.4.3.1 Clarity**

The information contained in the description must allow the Person skilled in the art to understand the technical problem and the solution provided by the polymorphic.

**3.4.3.2 Sufficiency**

The description must disclose the polymorphic sufficiently to allow the Person skilled in the art to reproduce it.

To comply with this criterion, there should be a comprehensive description of at least one form to achieve the polymorphic; this means that the essential steps and experimental conditions should be disclosed with enough detail to allow the reproduction of the polymorphous invented following the process that enables its obtaining. Additionally, the essential elements of the crystal must be disclosed in the description using techniques to characterize it (DRX monocrystal or powdered and TGA, DTA, and DSC thermal analysis methods) and provide, as a complement, structural information of the compound (Raman and IR spectroscopy or RMN-C13), as well as of the technical problem that the invention intends to solve and the other characteristic elements associated to the crystalline web; that is the case of the cell unit dimensions and the crystalline habitus that would allow a Person skilled in the art to understand the invention's contribution to the state of the art.

The disclosure will be considered insufficient if

- There is no description of the measuring methods used to determine the values of the structural and crystalline parameters of the polymorphic claimed;
- The preparation processes disclosed in the application are identical to those in the state of the art, but it is stated that a different polymorphic has been obtained; or
- All the preparation processes disclosed prepare the polymorphic claimed using seed crystals, but the process to prepare the seed crystals is not described.

Both cases, insufficient disclosure and inventive step of an invention related with a polymorphic, consider the same degree of expertise of

the Person skilled in the art.

**3.4.4 Examination of claims**

**3.4.4.1 Clarity**

No standard form exists, accepted universally, to report a polymorphous.

In many cases the difference between several polymorphous can be detected visually due to the differences in color or crystalline habitus of each form; hence, polymorphism can be detected using diverse experimental techniques; from the easy ones (such as the refraction index, dissolution rate, and observation in a polarized light optical microscope) to the more sophisticated analysis methodologies.

A polymorphic can be properly characterized in a claim using its physical chemical parameters such as:

1. The diffraction pattern of X-rays in mono crystal, which is specific for each polymorphous; so, if the claim characterizes the polymorphic using this pattern, no other information will be required.
2. The diffraction pattern of X-rays in powder (DRXP) measured between 5°, 2θ and 90°,2θ.
3. Raman and IR spectroscopies.
4. RMN-C13 spectroscopy.
5. Thermal analysis methods: TGA, DTA, and DSC

Diffraction of X-rays is the most useful technique to study polymorphism regarding the crystalline structure because the diffraction patterns of the various polymorphics always show substantial differences; that is the reason why the most representative intensity peaks must be included for the case of the crystal claimed.

Example:

The following is a polymorphic characterized by the IR, Raman, and RMN-13C spectrums and the DRX pattern in powder

Pat US6806280: a polymorphic form of the maleic acid salt of 5-[4-[2-(N-methyl-N-(2-pyridyl) amino) ethoxy] benzyl] thiazolidine-2,4-dione characterized because it shows>

- An infrared spectrum that shows the following peaks 1763, 912, 86 y 709 cm-1.
- A Raman spectrum that shows the following peaks 1762, 1284, 912 y 888 cm-1
- A Nuclear Magentic Resonance 13C spectrum that represents the following peaks 111.0, 113.6, 119.8, 129.1, 130.9, 131.8, 134.7, 138.7, 146.5, 152.7, 157.5, 169.5, 171.0, 178.7 ppm
- An X-ray powder diffraction spectrum which gives calculated lattice

spacings (dhkl) in the 2θ angles:
2θ Angles (°)9.9, 12.5, 13.1, 15.1, 15.5, 16.7, 18.9, 20.3, 21.2, 21.7, 22.1, 22.9, 23.4, 23.9, 24.6, 25.2, 25.7, 26.3, 27.1, 27.5, 27.9, 28.7, 29.1, 30.1, 30.5, 30.8, 31.3, 31.7, 32.9, 33.2, 33.8, 34.0
Spacing d (Å)8.97, 7.07, 6.78, 5.87, 5.72, 5.30, 4.69, 4.38, 4.19, 4.09, 4.02, 3.88, 3.80, 3.72, 3.61, 3.53, 3.46, 3.39, 3.29, 3.25, 3.20, 3.11, 3.07, 2.97, 2.93, 2.91, 2.85, 2.82, 2.72, 2.69, 2.65, 2.64
In this manner, a claim defined exclusively in terms of the "crystalline form (II) of a compound X" does not comply with the clarity requirement.

**3.4.4.2 Conciseness of the claim**

If the claims refer two few polymorphs, they will be considered as concise.

**3.4.4.3 Support of the claim in the description**

A claim of the polymorph will be considered duly supported in the description if it discloses:
- The physical chemical parameters of the polymorph claimed;
- The relevant experimental conditions of the measuring methods used to determine the characteristics of the polymorph claimed together with the characteristics of the crystal and its structure; and
- The claimed preparation processes of the polymorphs.

**3.4.5 Patentability examination**

The examination of a polymorph patent application is performed in the conventional order. That is, the novelty first and the inventive step next.

**3.4.6 Novelty examination**

The novelty examination must be performed as follows:
1. Identify and list the special technical characteristics of the polymorph of the independent claim, that is, the peak values of the X-ray diffraction pattern in mono crystal; or the X-ray diffraction pattern in powder; Raman, IR and RMN-C13 spectroscopies; and the TGA, DTA, or DSC diagrams and curves.
2. Identify the technical characteristics of the polymorphs of the state of the art.
3. Compare the essential technical characteristics of the polymorph claimed with those of the state of the art.

If the essential characteristics of the polymorph claimed had been disclosed specifically in one single document of the state of the art, the polymorph will be considered not new.
Now then, the polymorphs of a known compound in the state of the art are considered new if, given its essential technical characteristics,

they have a structural form generated by the way, not described in the state of the art, in which its molecules position and relate within the crystalline web.

If a polymorph claimed is equal to other in the state of the art because it has been produced from the same reagents and process, even though the state of the art does not mention the same particular characteristics defined in the claim under study (DRX mono crystal or in powder together with two characteristics chosen from the Raman, IR or RMN-C13 spectroscopies), an initial objection for lack of novelty of the crystal and the process must be issued, taking into consideration that if said characteristics in the polymorph disclosed in the state of the art were measured, it would be highly probably to obtain the same values.

If the applicant demonstrates using valid arguments or comparative trials/tests that the characteristics of the polymorph claimed are actually different to those of the state of the art, the novelty would be established.

Example: the following are two polymorphs with the same compound and differ to each other in that one of them is the crystal of the compound and the other is the methanolate solvate. Given that they are different crystals, each one has an X-ray diffraction pattern in powder with peak values in 2θ different and characterized as follows:

Pat US 52946151: A crystalline polymorph of 1-(4-amino-6,7-dimetoxy-2-quinazolyne)-4-(2-tetrahydrofutoyl) piperazine monochlorhydrate characterized because the X-ray diffraction pattern in powder has peak values in two theta of 5.5° ± 0.2°, 10.6° ± 0.2°, 11.1° ± 0.2°, 16.7° ± 0.2°, 19.4° ± 0.2°, 21.3° ± 0.2°, 22.0° ± 0.2°, 22.7° ± 0.2°, 23.1° ± 0.2°, 24.4° ± 0.2°, 24.9° ± 0.2°, 25.5° ± 0.2°, y 27.8° ± 0.2°.

Pat US 5412095: The compound having the name 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-(tetrahydro-2-furoyl)piperazine monohydrochloride methanolate characterized by peaks in the powder x-ray diffraction pattern at values of two theta of 5.09°35 0.2°; 9.63°±0.2°; 11.64°±0.2°; 15.32°±0.2°; 16.63°±0.2°; 21.25°±0.2°; 22.24°±0.2°; 22.28°±0.2°; 26.62°±0.2°; and 28.93°±0.2°.

**3.4.7 Inventive step examination**

The inventive step examination of the polymorph claimed will be carried out using the problem-solution approach as follows:

1. Identify the closest state of the art to the invention

The closest state of the art to the polymorph claimed will be the document that discloses the same compound although it might not define a particular crystalline form or refers to a different crystalline

form but mentions the larger number of physical technical common characteristics with the polymorph claimed; and its technical purpose is similar or equal.

2. Determine the difference between the invention claimed and the closest state of the art.

3. Define the technical effect caused by the difference and directly attributable to it.

The technical effect can be determined if it is mentioned in the application's description; but some applications might not evidence the technical effect or it could not be mentioned in the application.

4. What is the objective technical problem?

The examiner must deduct what is the objective technical problem in the light of the closest state of the art and based on the technical effect provided by the claimed polymorph. Therefore, the objective technical problem can be different from the subjective technical problem filed at first by the applicant.

Most of the problems to be solved by polymorphs are:

- Obtain an alternative physical form of a known compound to achieve the same technical effect, or
- Obtain an additional physical form of a known compound with different or improved properties related with:

| Crystalline properties | Technologic properties | Thermodynamic properties | Spectroscopic properties | Kinetic properties | Surface properties |
|---|---|---|---|---|---|
| Molar volume | Hardness | Fusion temperature | Vibration | Dissolution rate | Interfacial tension |
| Density | Compression | Sublimation temperature | Rotation | Reaction speed in solid state | Crystalline habitus |
| Refraction index | Flow speed | Internal energy | | Stability | Particle size distribution |
| Conductivity | Thermal expansion | Entropy | | | |
| Hygroscopicity | | Calorific capacity | | | |
| Crystalline properties | Technologic properties | Thermodynamic properties | Spectroscopic properties | Kinetic properties | Surface properties |
| | | Free energy | | | |
| | | Chemical potential | | | |
| | | A Thermodynamic activity | | | |
| | | Steam pressure | | | |
| | | Solubility | | | |

The objective technical problem can be stated as follows: "how to modify the closest state of the art to achieve the technical effect

provided by the polymorph claimed."
If there is no evidence of a technical effect, the objective technical effect will be considered as "the need to provide an alternative polymorph of… (Known compound)."
5. Verify that the objective technical problem is identified in the application.
Taking into account the information included in the description of the application and the information provided by the applicant, it is necessary to verify that the objective technical problem is identified through obtaining the crystalline structure of the compound.
6. Determine if the polymorph is inventive.
If the answer to the following questions is affirmative: (a) would a Person skilled in the art recognize the problem? (b) Would this person solve it in the form claimed, based on the state of the art, without making an inventive effort? Then, it can be concluded that the polymorph claimed is obvious because:
- If the technical problem has been defined as "…the need to provide an alternative polymorph of…" that produces the same or similar effect, it can be concluded that the closest state of the art describes the solution, so the polymorph claimed is not invention.
- If the technical problem has been defined as "…the need to provide an alternative polymorph of…" that produces the same or similar effect, it can be concluded that the closest state of the art describes the solution, so the polymorph claimed is not invention.
If the polymorph claimed is the obvious consequence of establishing routine experimental condition, or if its polymorphic structure is an alternative that could have been predicted with confidence using computer models, then it will not be considered inventive. But, if thanks to its crystalline structure the polymorph claimed solves the objective technical problem unexpectedly, for example because it shows superior pharmaceutical efficacy to those of the amorphous equivalents or the other crystals, the polymorph will be considered inventive.
If there are no indications in the state of the art that might induce the Person skilled in the art –faced with the technical problem– to obtain an alternative physical form of a known compound or modify the polymorph or the known product to achieve a polymorph equal to the one claimed, the invention is not obvious because there is no knowledge in the state of the art that would lead the knowledgeable person to the polymorph claimed and, consequently, the polymorph has inventive step.
- If there are indications in the state of the art that would induce

the Person skilled in the art –faced with the technical problem– to obtain an alternative physical form of a known compound or modify the known polymorph to achieve a polymorph with different or improved but unexpected properties, based on the state of the art, then the invention is obvious because there would not be inventive effort.
But if the polymorph claimed has an unexpected effect upon the form of the closest state of the art, it will be considered that it is inventive.
Similarly, the examiner must evaluate if the process to obtain the polymorph implied creative activity in a way that, if the technical effect is unexpected, the process will be considered inventive and the process can be patented if the polymorph prepared using this process is inventive.

**3.4.8 Industrial applicability**

The various polymorphs of a given compound, which properties are studied and controlled, can be used in the pharmaceutics industry and other industries of the chemical sector related with paints, pigments, explosives, and food (chocolate, fat, etc.).

**3.4.9 Unity of invention**

In order to establish if a group of polymorphs claimed fulfill the requirement of unity of invention, it is necessary to determine the closest state of the art to the crystalline structures, and if there is a group of (new and inventive) distinctive characteristics that differ them from the state of the art. If it is possible to conclude that this group of distinctive characteristics is the same for each polymorph claimed, then they are considered to have unity of invention among them.
Example:
Claim 1:
Polymorph B of compound X
Polymorph C of compound X
Polymorph D of compound X
Monohydrate of compound X
Ethanolic solvate of compound X
The new and inventive technical characteristic that is common to a monohydrate of compound X and ethanolic solvate of compound X is that both are solvates.
The closest state of the art teaches that polymorph A of compound X and polymorphs B, C, and D differ from polymorph A because they present a unique specific crystalline structure not shared with any other polymorph. Consequently, no new or inventive technical characteristic

exists that are common to polymorphs B, C, and D claimed; hence, there is no unity of invention, and the application contains four different inventions, namely

1. Polymorph B of compound X,
2. Polymorph C of compound X,
3. Polymorph D of compound X, and
4. Monohydrate of compound X and ethanolic solvate of compound X.

### 3.5 Selection patent

#### 3.5.1 What is a selection patent?

It is a patent that claims one single element or a small group of elements that belongs to a broad known group of elements.

#### 3.5.2 Examples

##### 3.5.2.1 Selection from two or more lists

If a document in the state of the art discloses two or more lists of elements, an invention that consists of the selection of elements from both lists is considered new.

Example:

If the state of the art discloses compositions that contain:

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.

Then, the invention of a composition containing aspirin and vitamin C is new.

##### 3.5.2.2 Selection of sub-ranges

The selection of a sub-range that has not been explicitly mentioned in the known broad group or range is considered new if it complies with the following three conditions:

- The selected sub-range is narrower than the known range
- The selected sub-range is sufficiently far from the disclosed range, defined by the examples and ends.
- The selected sub-range is not an arbitrary example of the state of the art but a new invention.

Examples:

| Solicitud | Estado de la Técnica | ¿Es Nueva? |
|---|---|---|
| n = 1 | n = 1 – 8 | No |
| n = 8 | n = 1 – 8 | No (1) |
| n = 5 | n = 1 – 8 | Si (2) |
| eje de metal | eje de cobre | No |
| 120 – 150 ºC | 120 ºC | No (3) |
| 125 – 130 ºC | 120 – 150 ºC | Si (4) |
| 120 – 150 ºC | 130 – 160 ºC | No (5) |

(1) n = 8 is not new because it is equal to one of the ends known.
(2) n = 5 is new because it is different to the ends of the known range, and because it is not described explicitly in the previous document.
(3) 120 – 150 °C is not new because one of its ends is equal to one of the ends in the known range.
(4) 120 – 130 °C is new because it is a narrower range than the known range, is far from the known ends, and is not explicitly described in the examples of the state of the art.
(5) 120 – 150 °C is not new because it includes one of the known ends (139), has a sub-range (130-150) that is common to the known range and, also, value "150" is mentioned explicitly in an example of the state of the art.

Example 2:
Claim 1: Titanium alloy that contains 0.6 to 0.7% of nickel and 0.2 to 0.4% of molybdenum.
State of the art: it describes a titanium alloy that contains 0.65% of nickel and 0.3% of molybdenum.
Since the contents of nickel and molybdenum in the state of the art are particular, they annul novelty of the general contents claimed.

**3.5.2.3 Overlap or ranges**

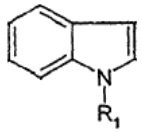
If a range claimed overlaps a previously disclosed range but provides a new technical effect, the previous document does not mention a specific example within the overlap interval and the end of the known range is excluded through a disclaimer, the range is considered new.
If a range claimed overlaps with a previously disclosed range, and does not provide a new technical effect, the previous document does not mention a specific example within the overlapping interval and the end of the known range is excluded through a disclaimer, the range is

considered new.

**3.5.2.4 Selection in chemistry**

Example:

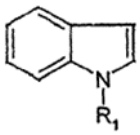
The claim refers to compounds of formula:



in which

R1 is alkyl $C_{3-5}$

A document in the state of the art describes a broad group of compounds of general formula:



in which

R1 is alkyl C1-20

If the specific group of compounds claimed in which R1 is alkyl C3-5:
- It is not explicitly described in any precedent of the state of the art by its chemical name nor its chemical formulation;
- It is far from the examples of the state of the art (compounds in which R1 is alkyl C16-17) and the ends (alkyl C1-20); and
- Shows an unexpected technical effect, not described in the state of the art.

Said specific group claimed is new (it is considered a selection) and has inventive step.

**3.5.3 Examination method**

The examination of a selection patent application is performed in the conventional order, that is, first the novelty and then the inventive step.

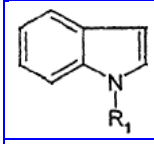
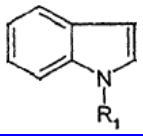
**3.5.4 Novelty examination**

A general formula in the state of the art does not annul the novelty of a compound or subgroup of claimed compounds included thereto. Otherwise, a specific compound in the state of the art annuls novelty of a general formula claimed.

A claimed compound formed by the selection of a specific substitute from a single list of substitutes of a formula in the state of the art is not new. This because the listing of all the possibilities for one single substitute is equivalent to the listing of all the specific compounds. But a claimed compound formed by the selection of one or

more substitutes from two or more lists of substitutes of a formula in the state of the art is new.
The novelty examination must be performed as follows:
- Identify and list the essential technical characteristics of the independent claim
- Identify the technical characteristics of the documents in the state of the art
- Compare the essential technical characteristics with those of the state of the art using a matrix like the following:

Comparison of the essential technical characteristics with those in the state of the art:

| Essential characteristics | D1 |
|---|---|
|  |  |
| $R_1$ | $R_1$ |
| alquil$C_{3-5}$ | alquil$C_{1-20}$ |
| | |

If the specific group of the compounds claimed is not explicitly described in any precedent of the state of the art by its chemical name or chemical formulation and is far from the examples in the state of the art and the ends, said group claimed is new (selection).
But if the essential characteristics of the group of compounds claimed had been disclosed specifically in a single document of the state of the art, it will be considered that the claim is not new.
Having accepted the fact that "what is general in the in the state of the art des not annul the novelty of the particular issues claimed, and what is particular in the state of the art annuls novelty of the general issues claimed", the examiner will understand that a product claimed formed by the selection of a specific element, based on a single list of product elements in the state of the art, is not new because the listing of all the possibilities of a single element is equivalent to the listing of all the specific products.
But a product claimed formed by the selection of two or more elements, based on two or more lists of elements of a product of the state of the art, is new. In such case, the examiner must consider that the selection patent is new since "a general expression of the state of the art does not annul the novelty of a particular element claimed and that is included in the general expression."

However, when the elements of the application and a document of the state of the art overlap, that is, a subgroup of the products claimed is known, the examiner will consider that the claim is not new, even if that document does not disclose some specific product of the subgroup.

**3.5.5 Inventive step examination**

A selection invention, for example, the selection of a subgroup of compounds of a Markush formula that is considered new has inventive step if all the compounds of the subgroup present a technical effect or activity not described in the state of the art and, besides, is unexpected.

As a result, if the examiner can demonstrate that some claimed compounds do not show that effect (for example, because the type of substitution makes insoluble or toxic the compound, due to the fact that the compound is unstable, etc.); so, it is considered that the entire group of compounds of the Markush formula does not have inventive step. And the applicant should restrict the application to those compounds that, although new, show activity.

So, the applicant will be required only to make a restriction based on documents demonstrating the compounds claimed that do not have said effect or activity. The examiner must determine the patentable matter and exclude or deny the one that is not, in compliance with the legislation and jurisprudence.

The inventive step examination must be carried out using the problem-solution approach as follows:

- Identify the closest state of the art to the invention
- Determine the difference between the invention claimed and the closest state of the art
- Define the technical effect produced by including said difference
- Define the objective technical problem
- Define if the selection is inventive. If the answer to these questions is affirmative: (a) would a moderately Person skilled in the art recognize the problem? (b) Would this person solve it in the form claimed, based on the state of the art, without making an inventive effort? Then, it can be concluded that the selection claimed is obvious.

A selection, for example of a product subgroup, considered new, will have inventive step if all the products of the subgroup show a technical activity or effect that is not described in the state of the art and, thus, is unexpected.

Therefore, if the examiner can demonstrate that some products claimed do not present said effect (for example, because they as insoluble,

toxic, or unstable compounds, etc.), then, the entire group of products claimed are considered to lack inventive step. And the applicant should restrict the application to those products that do have that effect or activity.

So, the applicant will be required to make a restriction based only on documents that demonstrate that the products claimed do not have said effect or activity; the examiner must determine the patentable matter and exclude or deny the one that is not in accordance with the state of the art and conforming to the legislation and jurisprudence.

A selection is considered inventive only when the elements selected have an unforeseen advantage. And it is denied when said advantage does not exist; conversely, it is a common activity to the broad group elements.

**3.5.5.1 Obvious selection and, thus, not inventive**

- The invention consists simply of selecting among a number of similarly probable alternatives.
- The invention relies on the election of particular dimension, temperature ranges or other parameters with a limited range of possibilities; and it is clear that those parameters could have been obtained through a trial and error routine or the application of common design procedures, so that the results obtained are absolutely predictable.
- The invention can be carried out through a simple direct extrapolation from the prior art.
- The invention consists of just selecting certain chemical compounds or compositions (including the combinations) within a broad field. And the compounds claimed do not have advantageous properties in respect with those of the state of the art, or said properties were expected by a moderately Person skilled in the art.

**3.5.5.2 Non-obvious selection and, thus, inventive**

- The invention involves a special selection in a process of particular operation conditions (for example, temperature and pressure) within a known range; said selection produces unexpected effects in the process performance or the properties of the resulting product.
- The invention consists of the selection of certain chemical compounds or compositions (including the combinations) from a broad field, where those compounds or compositions have unexpected advantages.

**3.5.5.3 Later strategy**

The examiner can suggest the applicant to restrict the application to the inventive compounds if, in view of the inventive step examination, it can be demonstrated that some of the compounds claimed do not show

an unexpected effect.

If the applicant ignores the restriction requirement, the objection will be ratified. If the applicant still ignores the examiner's suggestion to restrict the claim to the invention compounds of the application, it will be considered that the compounds of the selection are not inventive and the application will be denied. Otherwise, the application will be awarded.

On the other hand, if the applicant files comparative data, this information will be accepted as experimental evidence that the compounds of the selection have advantages in respect to those known in the state of the art.

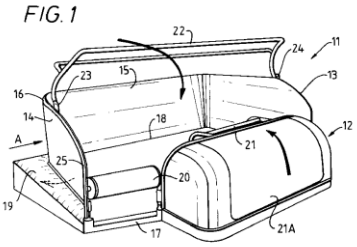
# 4 CHAPTER IV. ENGINEERING

## 4.1 Examples to determine the unity of invention

### 4.1.1 Example 1 Engineering

"Apparatus for pig breeding"

Content of the application. "Apparatus for use in farrowing and/or heating" (EP0513981):




The invention relates to a farrowing pen for a sow and piglets. In a second aspect the invention also relates to heating apparatus for heating piglets.

Identify the invention mentioned in first place and identify its essential technical characteristics and identify all the other possible inventions and their essential technical characteristics.

Understanding the application:

Claims 1, 6, and 7 are written as independent claims and, therefore, all of them should be searched. However, claim number 6 contains, at first sight, almost all the characteristics of claim 1. The only characteristic of claim 1 that is not mentioned explicitly in claim 6 is "means (16) for mounting the wall member". However, the aspect that the wall is inclined is explicitly mentioned in claim 6. Therefore, said means defined in claim 1, as well, must be present in the structure defined in claim 6. Clearly, the searches of claims 1 and 6 are closely related.

Consequently, on one hand, claims 1-6 must be searched and, on the other, claims 7-10.

Concepts mentioned by the applicant that underlie in the independent claims:

Claims 1-6:

Using a wall that can be inclined to the vertical and sloping downwardly and inwardly towards the farrowing area with a lower end of the wall member (15) spaced from the floor (17) of the farrowing area to provide a protected region beneath the member (15) for piglets to avoid crushing during lying down of a sow. See page 2, column 1.

Claims 7-10

A farrowing pen in which the heating means comprises a first heating means having an output of a relatively high intensity for attracting living creatures to a heated area, thus providing favorable conditions for their survival and viability while the sow will not suffer from suffering heat stress.

Lack of unity of invention can be stated in this case because both concepts defined in 2 are different and thus it is not possible to identify a single general concept that may be considered inventive.

On the other hand, it could be stated that both concepts defined have the same objective of "reducing the death rate of the piglets". However, it is important to keep in mind that this is not an invented concept by the examiner but a concept that clearly and without ambiguity bases on the application. Choosing one answer or another will influence later answers.

Do search and examine novelty and inventive step using the problem-solution approach to each possible invention

The search showed the document "Improvements in or relating to animal offspring-delivery units" (GB 953617A). It was found that if an animal is allowed to give birth in a non-confined environment, there is a high risk that the offspring be crushed by the mother.

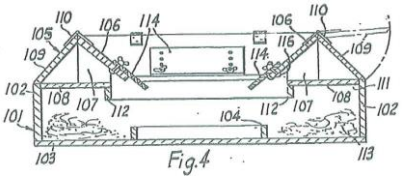


Fig.4

The document discloses a farrowing pen with inclined lateral walls to avoid the sow crush the piglets against the pen wall; the wall has a continuous surface and means to incline the vertical wall downwardly and inwardly, and the end of the wall is spaced from the floor of the farrowing area.

Examination of the first possible invention (Claim 1):

| Closest state of the art | GB 953617 A |
|---|---|
| Difference | A wall that can be inclined at an angle lying in the range 10° to 15° in respect to the vertical and inwardly to the farrowing area with the end of the wall spaced from the floor of the farrowing area. |
| Technical effect | Inside the pen there is an area |

| | |
|---|---|
| | for piglets to avoid being crushed by the sow. |
| Problem solved | How can the pen of GB 953617 A be modified to create an area in the pen for the piglets to avoid being crushed by the sow? |
| Is it obvious | No |

- The distinctive technical element of claim 1 related with document GB 953617 A is the fact that the walls are inclined 10° to 15°.

The inclination angle might seem a simple "preference" but, in context, is something more. The space gained as a result of the inclination is important because inside the pen an area is created in which the piglets can avoid being crushed by the sow.
Claim 1 is inventive in the light of document GB 953617 A, following the "problem-solution approach."
Examination of the second possible invention (Claim 7)

| Closest state of the art | GB 953617 A |
|---|---|
| Difference | Heating means having an output of a relatively high intensity |
| Technical effect | Heating means having an output of a relatively high intensity for attracting living creatures to a heated area, and heating means having an output of relatively low intensity to protect mother from heat stress. |
| Problem solved | How can the pen of GB 953617 A be modified to attract piglets while the mother is protected from suffering heat stress? |
| Is it obvious | No |

The distinctive technical elements of claim 7, related with document GB 953617 A are the heating means having an output of relatively high intensity and heating means having an output of relatively low intensity.
GB 953617 A does not suggest the heating means that have a high heat output with the purpose of attracting piglets, provide a heated area, offer favorable survival conditions, and viability while at the same time heating means with low intensity heat output is offered to protect the mother from heat stress.
Claim 7 is inventive in the light of document GB 953617 A using the problem-solution approach.
Compare the objective technical problem and the essential technical

characteristics of each possible invention:
The lack of unity of invention would be explained as follows:
There are no common technical elements to both inventions claimed because the distinctive technical elements of each invention are not identical.
Characteristics of claims 1 and 7 do not correspond to each other because they solve different non-related problems.
Since there is no relation between the technical elements of the different inventions, there is not a single inventive general concept.
Consequently, the requirement of Art 25 D 486 is not fulfilled.
Thus, the claims would be grouped as follows:
First invention: Claims 1-6, characterized by the structure of the wall.
Second invention: Claims 7-10, characterized by the heating means.

**4.1.2 Example 2 Engineering**

Application: CO 05-95209
Objection for lack of unity of invention showed in the first article 45
Title of the invention: Production of fuel
The problem stated in this application consists of how to obtain bio-diesel without using a great amount of catalysts along with its subsequent purification difficulties.
To solve this technical problem, an apparatus is developed to produce bio-diesel, which includes a reactor with an inlet to receive a mixture comprising a first reagent, a second reagent, a product of the reaction, and a solvent, an enzyme to facilitate the reaction, and a return mechanism.
Patent International Classification (PIC) in C10L1/08 and C10L1/85
Unity of invention (article 25 D 486)
This invention shows eight different common inventive technical concepts, namely:
· Group I: Claims 1-23. Apparatus comprised of a first reactor with an inlet, enzyme, outlet, and product return. Its particular characteristics are that it also has a vaporizer, L7L phase separator, a second reactor, and a short-path vaporizer.
· Group II: Claims 24-33. A system to produce alkyl ester that comprises a first subsystem that includes a reactor, and a second subsystem with a second reactor. The particular technical characteristics include a first and second return mechanism, and a first and second separator that can be a vaporizer or an L/L separator.
· Group III: Claim 34. Apparatus comprised by a reactor that has a

pipe, coupler, cartridge, inlet, enzyme, outlet, separation unit, and product return mechanism.

· Group IV: Claim 35. A system to produce alkyl ester that comprises a fires subsystem that includes a first reactor with a pipe, a first couple, a first inlet, enzyme, and outlet; a second subsystem that includes a second reactor with a pipe, a second coupler, and a second inlet, enzyme, and outlet.

· Group V: Claims 36-41. A system to produce alkyl ether that comprises a cartridge, identification device, and a controller.

· Group VI: Claims 42-44. An apparatus that comprises a cartridge that includes a lipase, a mixer, a vaporizer, and two phase separators.

· Group VII: Claim 45. An apparatus that comprises a vaporizer and a separator.

· Group VIII: Claims 46-48. An apparatus to produce alkyl ester that comprises a mixer, reactor, vaporizer, and separator.

| Essential technical characteristics | | Group I Claims 1-23 | Group II Claims 24-33 | Group III Claim 34 | Group IV Claim 35 | Group V Claims 36-41 | Group VI Claims 42-44 | Group VII Claim 45 | Group VIII Claims 46-48 |
|---|---|---|---|---|---|---|---|---|---|
| Reactor | 1st inlet | X | x | x | x | | | | x |
| | 1st enzym | X | x | x | x | | | | |
| | 1st outlet | X | x | x | x | | | | |
| | 1st return nechanism | X | | x | | | | | |
| | 1st pipe | | | x | x | | | | |
| | 1st coupler | | | x | x | | | | |
| | 1st cartridge | | | x | x | x | x | | |
| | 1st separation unit | | | x | | | | | |
| Second reactor | 2nd inlet | | x | | x | | | | |
| | 1st enzym | | x | | x | | | | |
| | 2nd outlet | | | | x | | | | |
| | 2nd return mechanism | | x | | | | | | |

| Essential technical characteristics | | Group I Claims 1-23 | Group II Claims 24-33 | Group III Claim 34 | Group IV Claim 35 | Group V Claims 36-41 | Group VI Claims 42-44 | Group VII Claim 45 | Group VIII Claims 46-48 |
|---|---|---|---|---|---|---|---|---|---|
| | 2nd pipe | | | | x | | | | |
| | 2nd coupler | | | | x | | | | |
| | 2nd cartridge | | | | x | | | | |
| | controller | | | | | x | | | |
| Mizer | | | | | | | x | | x |
| Vaporizer | | | | | | | x | x | x |
| 1st separator | | | | | | | x | x | x |
| 2nd separator | | | | | | | x | | |

The table above clearly shows the essential technical characteristics of the claims in each of the different inventive groups of this application and shows that there are no particular technical elements in each group.

Inventive groups I and II are different because the first is performed in a stage and the second in a double stage; and this, according to the design of the reactors, increases productivity as it is observed in examples 1 and 3 of the description where, in a two-stage process, the product obtained contains 96.10-99.24% alkyl esters, and in a single stage is just 86.55%.

Hence, groups I and III are different because group III has a pipe, a coupler, cartridge and separation unit; then, the reactor of group I does not reveal that it can have the enzyme supported in a cartridge, but inventive group III does.

Groups II and IV are different because group IV has a pipe, coupler, cartridge in each subsystem; also, reactor of inventive group II does not mention if it has the supported enzyme; and it consists of a separation unit and group IV does not mention anything about it.

Groups V and VI differ between each other because group V has a controller but not a mixer, vaporizer, and one or two separators, but group VI does.

Groups VI and VIII are different because one uses a cartridge instead of a reactor.

As it can be observed there is lack of unity of invention between the different groups because the inventive technical concepts are not common, due to the fact that by adding or eliminating devices or equipment the configuration of the apparatus or systems change, which

shows that the inventions are different.
The applicant is suggested to restrict the matter to be patented into a single common inventive concept specifying the technological advance over the state of the art. This is achieved defining the essential technical characteristics of the invention and showing the other particular characteristics as dependent characteristics without prejudice to the conciseness of the new claims, either independent or not.
The applicant can also make one or more divided applications in accordance to the groups of the inventive technical concepts filed in this application, indeed, without extending the initial object of the invention.
Patentability analysis
Despite the deficiencies showed in the description and the claim chapter, and highlighting the lack of unity of invention, the patentability examination will be performed to the firs inventive group of this applications (Claims 1-23)
Novelty
Regarding claim 1
Claim 1 says: "Apparatus comprised of a first reactor with a) an inlet to receive the mixture comprised by the first reagent, a second reagent, a reaction product, and an inert solvent that dissolves at least one portion of the first and second reagents; b) an enzyme to facilitate a reaction between the first and second reagents to generate more reaction products; and c) an outlet to remove the reaction product which includes the reaction product received in the inlet and the reaction product generated from the reaction between the first and second reagents; and d) a return mechanism that sends at least a portion of the reaction product in the outlet back to the inlet".
Regarding the state of the art
D1 describes a process to prepare the diglycerides which include: a tower packed with enzyme which includes a lipase to perform the esterification reaction between: 1) an aril donating group selected from a group that includes fatty acids, esters with short-chain alcohols and mixtures therefrom; 2) an acyl acceptor group selected from a group that includes glycerol, monoglyceride, and mixtures of them to obtain a reaction fluid to which the content of water or alcohol is then reduced and, subsequently, this reaction fluid is recirculated to the enzyme-packed tower thus achieving residence times of less than 120 seconds (Excerpt). Examples of esters with short-string alcohols includes alcohols that have 1 to 3 carbon atoms; for

example, methanol or ethanol (Page 5, lines 1-3). Also, a solvent as a hexane, octane, or ether of crude oil can be used in the reaction (Page 5, lines 26-27). Thus, figure 1 illustrates an apparatus to perform the process of this invention as follows: 1- dehydration tank; 2- mixing of crude raw materials; 3- agitator; 4- mixture of diglyceride (product); unreacted and intermediate materials; 6- enzyme-capped tower; 11, 12- capped-tower flow lines; 13- flow lines of the dehydration tank (Page 3, lines 10-20).

Regarding the application under study:

In accordance to that described in D1, it is observed that all the technical characteristics of claim 1 were already known in the state of the art as follows: entrance to the reactor (Fig.1 circulation path 15), enzyme (Fig 1 6: packed tower), outlet (Fig. 1 line 16), and return mechanism (Fig. 1 circulation path 11).

In view of the foregoing, the object of the invention taken from claim 1 has been disclosed identically in D1; therefore, this claim and its dependent claims cannot be considered new.

**4.1.3 Example 3 Engineering**

Application CO 06-73856

The invention is titled "Waterproof multilayer article permeable to vapor".

The problem stated in this application is expelling the condensation of transpiration in clothing or footwear which produces an unpleasant humid effect.

To solve this technical problem, the application under study provides a waterproof multilayer article that is permeable to vapor or air, which is structurally resistant and supported by itself.

International Patent Classification (IPC) in A43B13/12, B32B7/02

Unity of invention

No unity of invention exists between the four independent claims because the common inventive concept, waterproof multilayer article permeable to vapor, does not comply with the inventive step requirement in accordance to previous applications D1 and D6 (See patentability analysis for claim 1).

Moreover, procedure claims do not inherently have a common product.

Therefore, this invention presents 4 different common inventive technical concepts as follows:

· Group I: Claims 1-17. Multilayer article impermeable and permeable to vapor.

· Group II: Claim 18. Procedure to manufacture a multilayer article.

· Group III: Claims 19-20. Procedure to manufacture a multilayer

article.

· Group IV: Claims 21-22. Procedure to manufacture a multilayer article.

The applicant is suggested to restrict the matter to be patented into a single common inventive concept specifying the technological advance over the state of the art. This is achieved defining the essential technical characteristics of the invention and showing the other particular characteristics as dependent characteristics without prejudice to the conciseness of the new claims, either independent or not.

The applicant can also make one or more divided applications in accordance to the groups of the inventive technical concepts filed in this application, indeed, without extending the initial object of the invention.

Inventive step

Regarding claim 1

Claim 1 states: "Waterproof multilayer article permeable to vapor characterized because it comprises at least one first layer (11, 111, 211, 311) made in a permeable material to vapor, micro-porous, and hygroscopic that can adopt hygroscopic characteristics through time; and at least a second layer (12, 112, 212, 312) impermeable and permeable to vapor and hydrophobic."

Analysis of the differences in respect to the state of the art:

| Essential characteristics | D1<br>US5032450 | D6<br>US 4194041 |
|---|---|---|
| Waterproof multilayer article permeable to vapor | YES (Column 1, lines 45-46, 68; Col., 2 line 1) | YES (Column 2 lines, 25-29) |
| A first layer made in a permeable material to vapor | YES (Col. 1, lines 45-46, 68, Col. 2, lines 1). YES (Col. 15, lines 46-47) | YES (Col. 2, lines 45-51, Col., 10 lines 49-55 ) |
| Micro-porous | YES (Col. 2, lines 2-3) | NO |
| And hygroscopic | YES (Col. 1, lines 50-51) | NO |
| A second impermeable layer | NO | YES (Col. 4, lines 56-57) |
| And permeable to vapor | YES (Col. 2, lines 23-24) | YES (Col. 4, lines 32) |
| And hydrophobic | YES (Col. 2, lines 24) | YES (Col. 4, lines 32 y 56-57) |

D1 is the nearest document of the state of the art because it describes a permeable article to water and to water vapor, which consists of a

layer of a micro-porous material that comprises a polyolefin with an ultrahigh molecular weight and stuffed with a particulate material finely divided and an intercommunication net between the pores (Column 2, lines 4-22, 25-34, Column 15, lines 46-47) and at least one continuous polymeric layer hydrophobic and permeable to vapor (Column 2, lines 23-25) and that is useful in a wide variety of application where the impermeability and the transmission of water vapor is important (Column 17, lines 3-6)

Claim 1 of the Colombian application is different in D1 because the second layer is not impermeable.

The objective technical problem of this application is to make the article waterproof. The previous objective technical problem is solved in previous application D6 because it describes a breathing and impermeable article conformed by two layers where the external one is hydrophobic, porous, permeable to gases, and impermeable to water (Column 4, lines 31-33, 56-57).

Thus, a moderately Person skilled in the art with access to documents D1 and D6 could be encouraged to develop a waterproof multilayer article permeable to vapor according to the application under study.

In view of the above, the technical characteristics of the multilayer article in this application do not represent a technological advance in respect to the state of the art.

In conclusion, the inventive step of this claim and its dependent claims is affected because they are evidently derived from the state of the art and can be obvious for a moderately Person skilled in the art.

**4.1.4 Example 4 Mechanics**

CO 07-40577

Contents of the application: Surgical less invasive systems and methods

The object of this application consists of a surgical less invasive system that consists of means to expand an incision made to a patient; for example, a sequential dilator or retractor, an insertion needle and/or a needle to direct, locate, and insert screws or implants in the vertebrae, an exchanger that guides a wire to drill and that allows the location of screws or implants, a manual drill to make holed in the bone or vertebra, a screwdriver to screw or unscrew bolts or implants on the bone, a rod fixing unit that allows the insertion or tightening of the rods, as well as various fixing bolts and implants and a variety of rods to tie the heads of bolts or implants inserted to the bone.

The unity of invention study is done by following these steps:
Identify the invention mentioned at first, as well as its essential technical characteristics and the other possible inventions and their essential technical characteristics.
It is considered that there are various inventions because there are various products that include characteristics of annex products that are covered by the following claims:
Invention 1: Implant system compound by a spinal fixation device, a needle and a flexible portion according to claims 1, 9-14, 17, 18, 34, 36-38, 43-50.
Invention 2: Dilation mechanism, as per claims 2-8
Invention 3: Mechanism to implant and position the implant, according to claims 15, 16, 19-22, 24, 25. 39, and 40.
Invention 4: fixation device and device for spinal fixation, according to claims 22, 23, 34-36, 40-42.
Invention 5: Element to insert the fixation devices, according to claims 26-33.
Invention 6: Screwdriver, according to claim 37.
Taking into account that there is not a technical relation that would integrate this group of inventions under a single common general inventive concept, and that each inventive group tries to solve different technical problems and shows significant variations in the particular technical elements that configure them, the unity of invention requirement is not fulfilled.
Do search and examine novelty and inventive step to the first invention using the problem-solution approach.
The object of claim 1 and dependent claims 9-14, 17, 18, 34, 36-38 consists of an implanting system composed of a spinal fixation device, a needle, and a flexible portion.

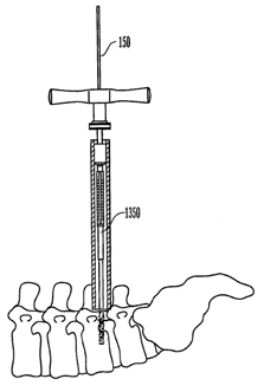



*Fig. 13B*

Document US 200220020255 published on 21/02/2002 discloses a retainer

to fix a bolt or implant during the surgery to insert it into the bone and uses a screwdriver attached to the device. The retainer has a free gripping device on its farthest end and has an expandable portion to receive the bolt or implant. Likewise, in its other side, it has at least one radial hole to receive the blocking sphere; this sphere holds the internal handle of the screwdriver to the retainer when passing through it allowing it to act as a single group when the screw or implant is about to be implanted to the bone. (Abstract, Pages 1 to 3 Fig. 1, Fls. 143 to 145, sheet 1 Paragraph 0012 to sheet 2 par. 0018).

Novelty:

When the claim 1 of the application under study is compared with the technical characteristics of the device disclosed in document US200220020255, it is observed that it contains all the essential technical characteristics of claim 1 as it is shown in the following table. In conclusion, the object of claim 1 is known because all its essential particular technical elements are revealed by the state of the art according to US200220020255, and the dependent claims 2 to 50 do not teach technical characteristics that make the invention new.

| NOVELTY STUDY | |
|---|---|
| Essential characteristics of the application under study | D1 US200220020255 |
| | The reference numbers in parenthesis correspond to the reference numbers of the elements of document D1 |
| | Retainer to fix and lock a bolt or implant, during the surgery to insert the implant to a bone. |
| A system to implant spinal fixation devices to vertebrae through an incision in the patient, which comprises | A system to implant spinal fixation devices (12, 28) to vertebrae through an incision in the patient, which comprises (FI 43 “Abstract”; FI 144, sheet 1, paragraphs (0005), (0006 to 0012); FI 144, sheet 2, paragraphs (0013 to 0018); FI 144, sheet 2; and FI 145, sheet 3, claim chapter, Figure 1) |
| A needle with a proximal end, a distal end, a channel from the proximal to the distal end, and at least one slot that intersects the channel. | A needle (12) with a proximal end (see fig. 1), a distal end (see fig. 1), a channel from the proximal to the distal end (see fig. 1), and at least one slot (36) that intersects the channel (see fig. 1), (FI 43 “Abstract”; FI 144, sheet 1, paragraphs |

| | |
|---|---|
| | (0012); FI 144, sheet 2, paragraphs (0013 to 0014); figure 1) |
| And a flexible portion to hold the fixation device | And a flexible portion (14) to hold the fixation device (22), (FI 43 "Abstract"; FI 144, sheet 1, paragraphs (0012); FI 144, sheet 2, paragraphs (0013 to 0018); figure 1) |
| In which at least one slot has a size and is configured to receive a long fixation device. | In which at least one slot (18) has a size and is configured to receive a long fixation device (22). (FI 43 "Abstract"; FI 144, sheet 1, paragraphs (0012); FI 144, sheet 2, paragraphs (0013 to 0018); figure 1) |

**4.2 Inventive step in mechanics**

The invention refers to a dining table. In the description the applicant describes the inherent problem to all the 4-leg tables, that is, that the table swings on irregular surfaces.

Technical problem: provide a 3-leg dining table that can be put on an irregular surface without swinging.

Independent claim: Dining table which upper table (part) is supported by just three legs and its center of gravity is between those 3 legs.

**4.2.1 Example of inventive step in mechanics**

CO 03-113218

Content of the application: can holder, piece in cardboard for the can holder and assembly method.

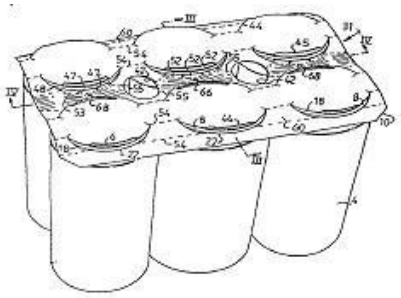
The object of the application consists of a holder that can collect a series of cans and includes at least two rows placed safely to connect the cans and block them in the form of a package-type assembly so that it can be lifted and handled without the risk of releasing them.

Inventive step examination:

The inventive step study is performed using the problem-solution approach, according to the following stages:

- Identify the closest state of the art to the invention.
- The closest state of the art to the can holder claimed is the document that discloses the same type of article and mentions the larger number of common technical characteristics to the holder and its technical purpose is similar or equal.
- The priority date considered to determine the state of the art related with the object claimed was 03/07/2001 and the documents related with the object are US469687 and WO9105716.
- The independent claims 1, 14, and 19 describe an element represented

by figure 1:



- Document US469687 discloses an apparatus and a method to form packages of articles piled up by using clip-type carriers. The machine uses a piling piece that uses a reinforcement fold to form a bowl with no external or complementary help to keep the group of cans together.
- Document WO9105716 discloses a multipack with a series of indentations in the round profile which size is smaller to the diameter of the can in its upper part and that, when pressured, locks in the round perimeter and below the can's rim.
- Determine the difference between the invention claimed and the state of the art.

Comparison table of the characteristics claimed.

| Claim 1 | CLOSEST STATE OF THE ART US469687 | WO9105716 |
|---|---|---|
| 1) Cardboard holder (31),<br>2) that connects several cans, generally cylindrical (4),<br>3) placed in at least two rows that have an inclined superior part and an upper lock (6) with a protruded round ring (8),<br>4) the holder is manufactured from a single flat raw piece (32) that has, for each can connected to the holder, two bent opposite slots (44, 45),<br>5) the external edges of the slots couple under the can rim (8) when the holder is assembled forming a package configuration. | YES | YES |
| Holding rabbets (42) adapted to be held using the fingers with the purpose of lifting and handling the package; they are located in the center part of the rough piece (32) of the holder, between the can rows (4). | NO<br>It has holding rabbets to be held with the fingers. | YES<br>It has elements to place the fingers to handle the pack easily |
| Oversized bowl-shape indentation (66) configured in the middle of the holder (31) between the holding rabbets (42) and | YES<br>It has bowl shape | NO |

| | | |
|---|---|---|
| the can rows (4). | indentation to strengthen the group of cans. | |

The nearest document is US469687 because even though it does not have the rabbets adapted to introduce the fingers, they show the bowl-shape indentation.

- Define the technical effect caused by the difference and directly attributable to it.

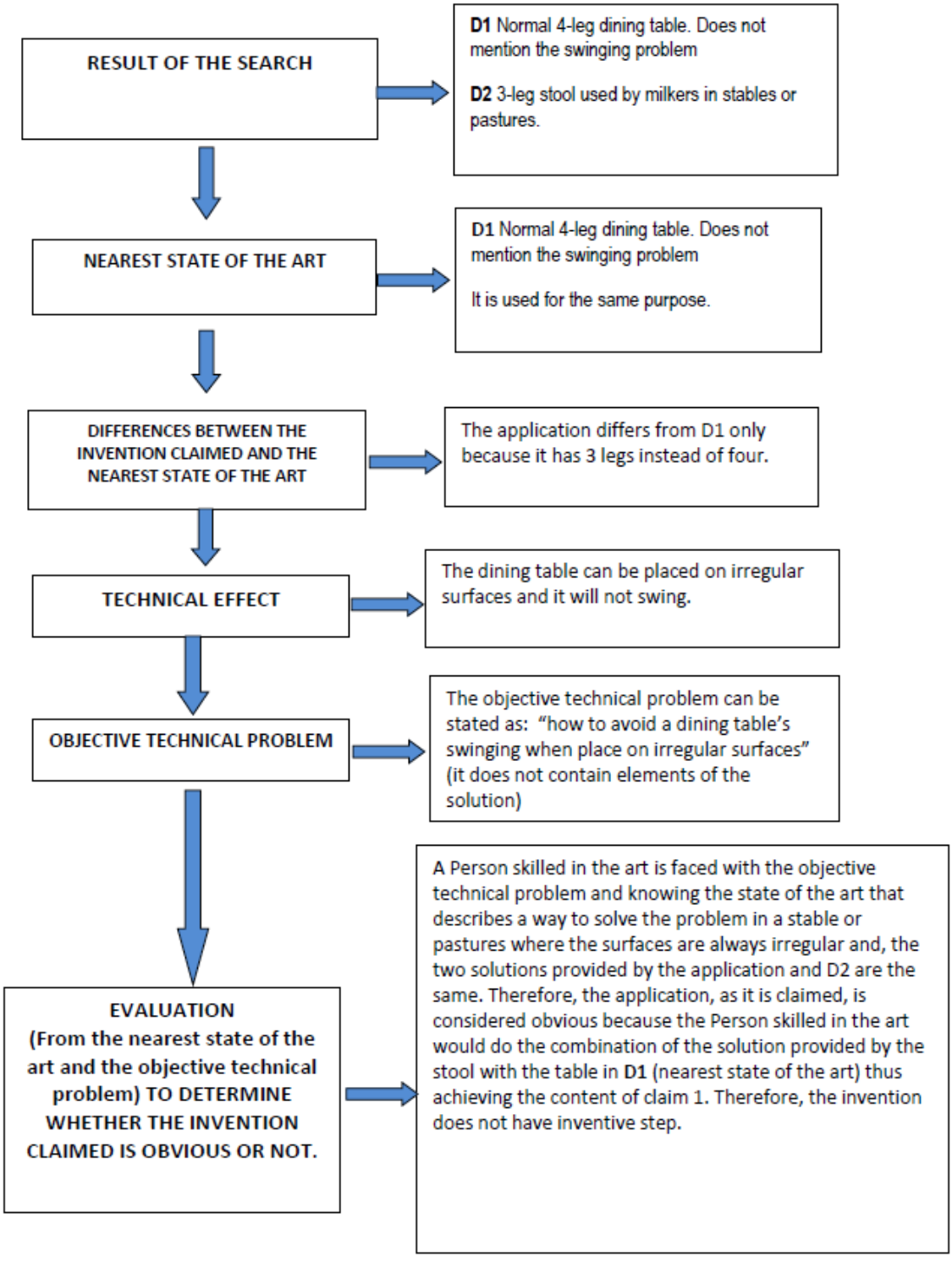
The technical effect produced by the holding rabbets consist on reinforcing the whole unit because it facilitates the packaging of the cans by making pressure with the fingers.

- What is the objective technical problem?

The objective technical problem consists of overcoming the lack of security of the holders that keep the cans together, while it connects, locks, and holds the cans in the form of a package configuration that can be lifted and handle without the risk of releasing them

- Define if the product is inventive

Document WO9105716 presents the same effect but with a different configuration because it discloses an article with the elements to place the fingers (21) that facilitate holding the system and manipulate the cans; it also shows indentation with the elements (17) and (18) to conform better the whole package; therefore, the solution claimed is obvious for a Person skilled in the art.


RESULT OF THE SEARCH
D1 Normal 4-leg dining table. Does not mention the swinging problem
D2 3-leg stool used by milkers in stables or pastures.
NEAREST STATE OF THE ART
D1 Normal 4-leg dining table. Does not mention the swinging problem
It is used for the same purpose.
DIFFERENCES BETWEEN THE INVENTION CLAIMED AND THE NEAREST STATE OF THE ART
The application differs from D1 only because it has 3 legs instead of four.
TECHNICAL EFFECT
The dining table can be placed on irregular surfaces and it will not swing.
OBJECTIVE TECHNICAL PROBLEM
The objective technical problem can be stated as: "how to avoid a dining table's swinging when place on irregular surfaces" (it does not contain elements of the solution)
EVALUATION
(From the nearest state of the art and the objective technical problem) TO DETERMINE WHETHER THE INVENTION CLAIMED IS OBVIOUS OR NOT.
A Person skilled in the art is faced with the objective technical problem and knowing the state of the art that describes a way to solve the problem in a stable or pastures where the surfaces are always irregular and, the two solutions provided by the application and D2 are the same. Therefore, the application, as it is claimed, is considered obvious because the Person skilled in the art would do the combination of the solution provided by the stool with the table in D1 (nearest state of the art) thus achieving the content of claim 1. Therefore, the invention does not have inventive step.

# 5 CHAPTER V. BIOTECHNOLOGY

## 5.1 Definitions

### 5.1.1 Biologic material

Biological material is any material that contains genetic information able of reproducing by itself or through a biological system such as a gen, plasmid, virus, microorganism, animal, plant and/or material originated therefrom and that does not have genetic information such as products derived from the genetic resource such as metabolism products, extracts, resins, etc.

### 5.1.2 Microorganisms, vectors, and nucleic acids

The examiner must keep in mind that the microorganisms are the organisms fitted with individuality that, unlike plants and animals, presents an elementary biological organization. Most of them are unicellular, although in some cases they might be kenotic organisms compound by multinuclear cells, or even multicellular. Microorganisms include bacteria, actinomycetales, fungi, virus, protozoa, and algae, etc.

Likewise, the examiner must remember that a biological vector is an agent of organic type that serves as a means of transmission; epidemiologic vector is an organism capable of carrying and transmitting an infectious agent; genetic vector is an agent that carries a strange or modified gen; viral vector is an unstable modified virus that allows the introduction of exogenous genetic material to the nucleus of the cell; AND vector is an organism that is used to transfer exogenous genetic material to other cell.

Also, the examiner will keep in mind that the nucleic acids are macromolecules, polymers formed by the repetition of monomers called nucleotides joined by phosphodiester bonds.

## 5.2 Formal examination

The examiner must keep in mind the considerations of the form examination of applications in other technical fields. However, if a patent application refers to sequences of nucleotides or amino acids, the examiner must require that the lists be filed separately from the description under the title: “List of sequences” and attached in digital format.

Now then, if the application refers to biologic material, the examiner must require that the deposit certificate of the strain (or hybridoma). And if the application refers to a biopolymer derived from a defined species and that is originated in Colombia, the examiner must require

the applicant to attach the access to genetic resources or derivate products agreement issued by the Ministry of Environment, Housing, and Territory Development or state the status of its processing.

**5.2.1 Description and claims examination**

**5.2.1.1 Deposit of biologic material**

The examiner must keep in mind that in the biotechnology sector it is necessary that the biologic material be deposited in an institution. The deposits performed before a well-known international authority, as per the Budapest Treaty, will be valid. The deposit must be done no later than the application's filing date or the priority date invoked.

If at the moment of the presentation of the application the biologic material has not been deposited yet, or although it was deposited the certificate has not been submitted yet, the examiner will encourage the applicant to attach the certificate. If the applicant fails to fulfill this requirement in the time established, the examiner will consider the application abandoned.

**5.2.1.2 Clarity**

If the application mentions lists of sequences of amino acids, the examiner will require that those lists be attached in a legible form for search purposes; if those lists are not clear enough, but the name of the protein is mentioned, the examiner will do the search per name. If the invention consists of a recombinant gen or a recombinant DNA fragment, a recombinant vector, transformed cell, modified polypeptide, or modified protein, fused cell, monoclonal antibody, etc., the description must disclose its identification, structure, and preparation.

**5.2.1.2.1 Recombinant nucleic acid**

- Defined from the nucleotide sequence stating the number of said sequence (SEQ ID No.)
- No definitions stating homology or identity percentages are accepted because this definition does not allow establishing the exact nucleotide sequence that it refers to.
- The nucleotide sequence must claim a recombinant or modified sequence; it must not be a sequence that exists in nature.

For example: Molecule of nucleic acid that codifies protein YYYY characterized because it consists of SEQ ID No. CCC.

**5.2.1.2.2 Polypeptide or recombinant protein**

- A polypeptide or recombinant protein must be defined from the amino acid sequence, indicating its number (SEQ ID No).
- Polypeptides or proteins must not be defined from the nucleotide

sequence because of the redundant character of the genetic code.
- No definitions stating homology or identity percentages are accepted because this definition does not allow establishing the exact nucleotide sequence that it refers to.
For example: Recombinant protein AAA (property or function) of SEQ ID No. BBBB.

**5.2.1.2.3 Recombinant vector**

- A recombinant vector can be described by specifying, at least, the type of vector and the recombinant sequence it contains.
e.g.: Recombinant plasmid vector that comprises the nucleotide sequence SEQ ID No. XXX.

**5.2.1.2.4 Modified microorganism**

- A transformed microorganism must be claimed by indicating the type of microorganism, its modification (sequence introduced or mutation performed) and its biologic deposit number.
- The mere indication of the microorganism deposit number does not allow defining nor limiting the invention because it is not a characteristic that can be compared with or defined in the state of the art.
e.g.: modified yeast characterized because it comprises the nucleotide sequence SEQ ID No. XXX with a deposit No. YYY.

**5.2.1.2.5 Monoclonal antibodies**

- A monoclonal antibody must be characterized from its function and structure. Additionally, it can be defined specifying the hybridoma that produces it.
- The structure of the antibody must indicate the amino acid sequence of the variable regions of the light or heavy chains of the sequences of the 6 CDRs of the light and heavy chains.
e.g.: Antibody molecule that joins a XXXX comprising a variable region of heavy chain with SEQ ID No. XXX and a variable region of light chain with SEQ ID No. YYY.

**5.2.1.3 Sufficiency**

The manufacturing process of the product must be described except where the product can be made by a Person skilled in the art.
O Particularly, the process to produce transformed cells including its origin and type of cell (this cell must not be gametic or germinal, because the organism transformed from this cell is not protected)
O Description of the gen or the recombinant vector introduced and its origin
O Description of the host
O Method to introduce the gen or the recombinant vector in the host

O Method to collect and select the transformed cell, or
O Means to produce it
In turn, the process to produce a polypeptide or recombinant protein must be described by:
O An indication of the means used to obtain the gen and identification of its origin
O Modified amino acid sequence or codification of the polypeptide or protein.
O Means to obtain an expression vector
O Identification and means to obtain the host.
O Method to introduce a gen in the host.
O Method to collect, select, or purify the polypeptide or the recombinant protein of the transformed cell in which the gen has been introduced.
O Means to identify the polypeptide or protein
The process to produce monoclonal antibodies must be described by:
O The structure of the antibody must be defined from its amino acid sequence (at least the sequence of variable regions or CDR segments of heavy or light chains)
O Indicate the structure and function of the antibody produced, including the information about the origin, changes made to it, and antigen to which it joins.
O Indicate the means to obtain or produce immunogen, and immune response obtained from it.
O Immunization method and target organism of the immunization
O Means to identify the monoclonal antibody
O Method and identification of the hybridome produced, if any
The process to produce a vaccination composition must be described by:
O The vaccination composition must be defined from the immunogenic elements that compose it and their proportion.
O The immunogenic elements, as the case may be, must be defined from an amino acid sequence (if they are modified or a specific fragment of a protein), and their origin must always be indicated.
O The claimed vaccination composition must be disclosed, indicating adjuvants, excipients, and other elements of the trial formulation.
O Immunization method and target organism of the immunization
O Disclose immunization trials.

**5.2.2 Patentability exclusions and exceptions**

These topics were treated in the numeral that corresponded to the general guide; there you can find examples related to the biotechnology sector. The examiner is referred to that concernin the content

examination of the applications.
However, the following examples illustrate the topics associated to the therapeutic methods in biotechnology:
A modular method together with the activities of receiver X and Y in mammal cells that are sensible to X-Y, which comprises:
- Contacting the cells with an antibody,
Where the mammal cells are breast cancer cells or thyroid cancer cells.
Method to inhibit the growth of a cell that expresses the glucotip CA6, which comprises contacting a cell that expresses said glucotip with the cytotoxic conjugate XXX.
Given that these claims address a treatment method, the examiner will consider that they are not patentable.
The following is an example of a claim related with a diagnostic method that the examiner will consider not patentable:
A method to determine the regression, evolution, or initiation of a pathologic disorder, characterized by an increased expression and/or activation of the human receivers X and Y, relative to the normal, which comprises placing a detectable catheter that is specific for said human receivers, to a patient suffering from said disorder, under conditions that favor the formation of a complex catheter/receiver.
On the other hand, the existing microorganisms in the nature are not patentable in accordance to the legislation. However, they can be patented when they are modified and have an industrial applicability.

**5.3 Patentability examination**

**5.3.1 Novelty**

A microorganism that is in the state of the art, although it has not already been commercialized or deposited before a deposit authority, it is understood that it has been made available for the public and, thus, annuls the novelty of the invention under study.
The examiner will perform the novelty evaluation conforming to the method explained before.
However, the examiner will consider the following cases:
- If a recombinant protein is new, the examiner will consider that the nucleic acid that codifies it is new, too.
- If the application claims a new process to prepare a known recombinant protein, the examiner will consider that said protein is not new because it has the same amino acids sequence of the protein in the state of the art.
- If an antibody X claimed, defined by its function and structure that joins to an antigen A is new, any other antibody in the state of the

art that joins to that same antigen does not affect novelty of the antibody X; it would only affect novelty if it had the same epitope or the same structure of the antibody X.

**5.3.2 Inventive step**

The examiner will perform the inventive step evaluation using the problem-solution approach explained before.

The following situations illustrate the examiner about this topic:

- When a recombinant protein defined from a different amino acid sequence has a surprising technical effect when compared with the natural or modified known protein, the recombinant protein claimed has inventive step.
- If both the vector and the nucleotide sequence inserted are known, an invention or a recombinant vector obtained from the combination of both will not have inventive step. However, if an invention of a recombinant vector with a specific combination of nucleotide sequences can produce a surprising technical effect when compared with the state of the art, the invention will have inventive step.

**5.3.3 Industrial applicability**

The examiner must take into consideration that if the matter claimed, either a recombinant nucleic acid, a polypeptide, protein, vector, microorganism, or monoclonal antibody can be produced in the industry, it will have industrial applicability.

**5.4 Unity of invention**

Multiple polynucleotides without structural and functional bonds between them

Claim 1: Isolated polynucleotide chosen in the compound group of the nucleotides sequence SEQ ID No. 1-10.

According to the description, the polynucleotides claimed are ADNc of 500 pairs of bases obtained from a human liver ADNc bank. These polynucleotides with different structures can be used as probes that allow obtaining complete AND, even when the biological function or activity of the corresponding proteins is not described. Also, the polynucleotides claimed are not equivalent among them.

No known state of the art exists. Until now, no human liver ADNc bank has been constituted.

It will be considered that the polynucleotides of claim 1 have an identical or corresponding technical element in common if the variations have a common property or activity and are related by an important structural element that is essential for said common property or activity.

In this example, the description does not establish that all the polynucleotides of sequence SEQ ID No.: 1-10 have a common property or activity. Even if each sequence can be used as a probe to isolate its complete ADN, a probe derived from the sequence SEQ ID No. 1 cannot be used to isolate the sequences SEQ ID No. 2-10, respectively, due to the lack of equivalence between the sequences SEQ ID No. 1-10.
Also, due to the fact that the polynucleotides are not equivalent among them, they do not have a common structure, that is an important structural element. The structure sugar-phosphate cannot be considered as an important structural element because it is a common element to all the nucleic acid molecules. Consequently, the 10 polynucleotide molecules are not related by an important structural element and cannot be considered to have a common identical or corresponding technical element.
The simple fact that fragments of polynucleotides derive from the same source (human liver) is not enough to comply with the unity of invention criterion.
Those polynucleotides do not have a common activity or property, or common structure. As none of the two conditions are fulfilled, the group of polynucleotide molecules claimed does not comply with the unity of invention requirement (a priori).
A possible group could be filed as follows:
Inventions 1-10: Polynucleotides with the designation SEQ ID No.: 1-10.

## 6 CHAPTER VI. COMPUTER-IMPLEMENTED INVENTIONS

### 6.1 Patentability examination

The following instructions are the guidelines for the examiner to determine if the matter claimed by the applicant is eligible for patentability study.

To start the study that would determine if the application can be eligible for a patentability study, the examiner must keep in mind that the following criteria must be fulfilled:

(1) The invention claimed must be addressed to one of the two acceptable legal categories under article 14 D 486: Product or Procedure.

(2) The matter claimed must not be completely addressed to a patentability exception of those listed in article 15 D 486.

The following two analysis steps are used to evaluate this criteria:

### 6.2 Development of the first criterion

In the first part of the evaluation the examiner must ask: "is the matter claimed eligible for patentability for being a product or procedure?"

The object of the application must be addressed to one of the two categories of the patentable matter: products or procedures. Otherwise, the matter claimed will not be eligible for a patentability study and must be rejected, at least for this reason, by virtue of article 15 D 486.

Next, an abstract of the definitions of Procedure, Machine, Product, Compositions is submitted to the examiner.

Procedure, method or process: this is an action or series of actions or steps connected to a determined machine, apparatus, or device, or to the transformation of a particular article into a different status or object.

Machine: It is a concrete, tangible object that has parts or certain devices and is the result of the combination or interaction of said devices. This includes all the mechanical devices or the combination of mechanical forces and devices to perform some certain function and produce a determined effect or result.

Product: it is an article produced from the raw or prepared materials to give these materials new forms, qualities, properties, or combinations, either through manual tools or using machinery.

Compositions: All the compositions of two or more substances and all the compound articles, either resulting, from instance, from a

chemical joint or a mechanical mixture of gases, liquids, powders, or solids.
Examples of non-eligible matter for a patentability study because they are not considered inventions, without limiting to these examples:
The temporary form when transmitting a signal, for example, or the spreading of an electric or electromagnetic signal per se.
An organism of natural origin.
The human being, per se.
A legal contractual agreement between two parties.
A game defined as a set of rules
A computer program as such.
A company

**6.3 Development of the second criterion**

In the second step of the evaluation the examiner must ask: "Is the matter claimed within what is considered a patentability exception? Namely: discoveries, scientific theories, mathematics methods, the whole or part of living things as they are found in nature, plans, rules, and methods to exercise intellectual activities, computer programs, and logical support as such, and the other matter not considered inventions under Article 15 D 486; or ask: Can the matter claimed be considered a Practical Application?
It is very important to keep in mind that the object claimed must not be completely addressed to a patentability exception. If so, the matter claimed is not eligible for study and must be rejected by virtue of Art. 15 D 486.
Notwithstanding the foregoing, the examiner must also know that there is the possibility to study an application that claims matter considered a patentability exception.
It is important to bear in mind that if the application of the matter claimed, although it might be a patentability exception, is limited to a specific practical application, it can be eligible for study.
To clarify this concept, it is important to clarify that a practical application refers to how non-patentable matter can be applied in a product or real process. That is, when the non-patentable matter reduces to a particular practical application, having a real application, then the practical application claimed evidences that the matter claimed is no longer abstract or merely mental, and does not cover substantially all the possible modes of a law of nature or a natural phenomenon.

### 6.4 Practical aspects

#### 6.4.1 Product

##### 6.4.1.1 Machines, manufacture, composition of matter (three categories of product)

If the product claimed is within one of the previous three product categories and does not claim matter that is not considered an invention, such as an abstract idea, mathematical algorithm, law of nature, or natural phenomenon, it will be considered as a patentable object. If part of the application claims non-acceptable matter under Art. 15, it will be important to determine if said non-acceptable matter has been applied in a practical form to the product claimed.

Machines, manufactures, and compositions considered patentable matter are not of natural origin; they are products that are typically formed by elements or parts of tangible elements that represent a practical particular or specific application of an invention. Therefore, for these categories of products, a practical particular application is normally evident when it is based on the limitations of the claim that define its tangible particular field.

In other words, a particular practical application is an idea that is tangibly applied to a non-abstract structure, that is, when a law of nature or natural phenomenon is applied practically to a structure, limiting the idea to a particular application.

For example, a cup is the tangible application of the abstract idea of containing a liquid and is a limited modality of the idea (that is no longer abstract); other example could be a latch of a magnetic door, which is the tangible application of the concept of magnetism; however, it does not cover the entire concept of magnetism, but is a limited application of this concept.

A claim including terms that imply that the invention is directed to a product, for example, "…a machine that comprises…", but does not include tangible limitations in view of its reasonable broader interpretation, will not be limited to a practical application; conversely, it will comprise the total concept on which the invention is based. Said claim is not acceptable because the matter claimed would be extended to cover all the aspects of the application of the abstract idea, law of nature, or natural phenomenon.

A claim that includes non-patentable matter and which reasonable broader interpretation is aimed at a tangible field made by men (for example, a structure) with a real application, it is limited to a practical application, that is, the object matter that has been claimed practically. This is why a claim must be evaluated as a whole to

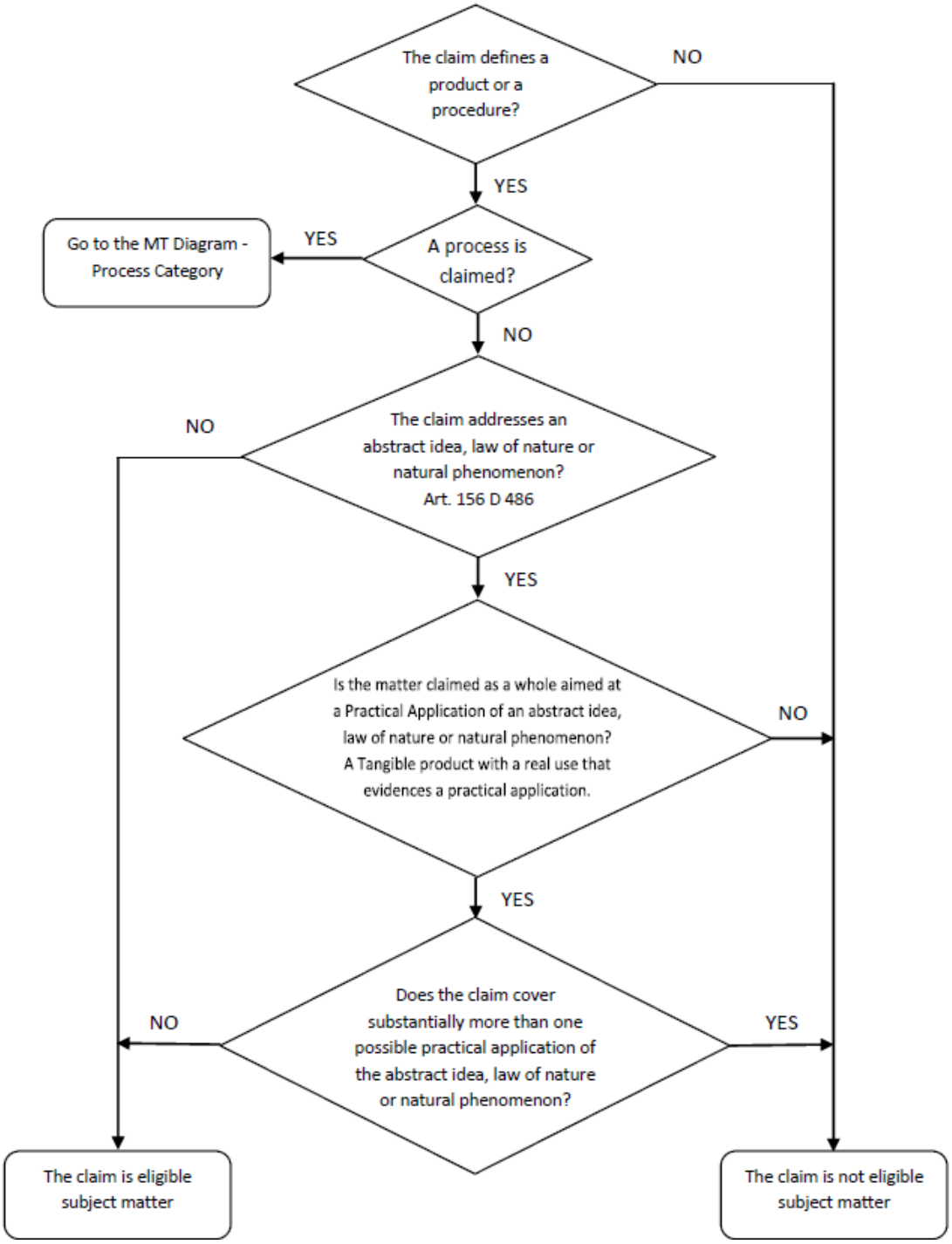
conclude that it is eligible matter for patentability study.
Once the practical application has been established, the limit of the matter claimed must be evaluated to determine if there exists admissible matter that covers substantially all the possible practical applications of the excepted matter; in this case, the claimed matter is not patentable (because it is not a reasonable interpretation in a tangible and real field); but, if the claim covers only a particular practical application of the excepted matter, this claim is eligible for the patentability study.
The matter considered not eligible for a patentability study is frequently claimed as descriptive matter.
The matter described must be evaluated by the examiner to determine if the matter has a functional relation with the underlying structure, in order to determine if there is a patentable distinction in respect with the state of the art or it is simply non-functional matter that does not establish a patentable difference.
For example, the printed material in an object or simple data stored in a memory are typically non-functional described matter that would not create a patentable distinction in respect to the state of the art. On the contrary, an electronic board or a computer program with executing instruction is often interpreted as a base structure, together with the functional descriptive material, that could create a patentable distinction in respect with the state of the art.
The following examples teach the difference between a tangible execution showing a particular practical application and an abstract concept with no practical application.
1. A claim of a machine composed of a number of structural elements that work together in a specific configuration based on a mathematical relation, such as a series of gears, pulleys, or belts, will have structural limitations that show that it is a tangible object and evidencing that the mathematic relation is a practical application. Also, said tangible materialization is limited by the structural configuration claimed and would not cover all the possible practical configuration in the execution of said mathematical relation. Thus, the claim would be eligible matter for a patentability study.
2. On the other hand, a claim directed to a machine defined as “A machine that works according to F=m•a”, but that does not include tangible structural elements in its broader reasonable interpretation, would cover an operation principle based on a mathematic relation where the scope of the claim would have no limit. Therefore, a non-tangible object would be claimed, but there would be no evidence of a

practical application; in such case the claim would cover, in all its possibilities, the mathematical concept of F=m • a and, thus, would not be eligible matter for the patentability study.

3. For example, a claim aimed at a computerized storage tangible means and legible by itself alone, which holds normalized structural limitations, in its broader reasonable interpretation to be understood as a manufactured object, could be eligible matter for the patentable study.

Adding complementary limitations to the claim such as executable instructions or stored data does not make the claim "unacceptable", provided the claim as a whole has a real application. The entire object claimed is still a tangible execution and qualifies as a product. Thus, the additional limitations in the claim will be evaluated to determine whether they distinguish from what is contained in the state of the art.

The tool to determine if the matter claimed in the product category is a particular practical application, the examiner must use the diagram P-T shown below.




### 6.5 Procedures

The examiner has the test of flowchart M-T as a tool to define if a procedure claim can be accepted as eligible subject matter for a patentability study.

To be accepted as eligible subject matter for a patentability study, a procedure claim must approve the test of flowchart M-T which ensures that the process limits to a particular practical application.

The test in flowchart M-T ensures that the process is not: an abstract idea, a mental process, or all the possible practical applications of a law of nature or natural phenomenon; therefore, not all the methods qualify to be accepted as eligible subject matter for patentability study.

According to M-T test, the procedure claimed should:

(1) Be connected to a specific machine, apparatus, or device.

(2) Be a specific transformation of an article determined to a different state or object.

The examiner must remember that a method claimed that does not require the application of a machine or does not produce a specific transformation of an article determined to a different state or object will not pass the test and will be rejected.

On the other hand, the sole presence of a link with a machine or a transformation is not enough to pass the test. When the examiner has identified the link with a machine or a transformation, he/she will have to establish that said link is with a particular machine of transformation of a specific article.

Also, the particular linked machine or transformation must comply with two requirements to pass the test of eligible matter for patentability study:

First, the use of a particular machine or the transformation of a particular article must define a significant limit for the scope of the claim. As a result, the fact of having a machine linked to a single activity field might not be enough.

Second, the application of the particular machine or the transformation of a particular object must imply more than an additional insignificant activity to the solution.

An additional insignificant activity to the solution means an activity that is not fundamental for the objective of the method invented by the applicant. For example, the collection of data to be applied in a procedure, when all the applications of the procedure that may require any form or data collection would not define a significant limit to the scope of the claim.

If the machine or the transformation is only present in a limitation of the application field or in a step that is merely an additional insignificant activity to the solution, the method claimed does not pass the M-T test, although there is a machine or a transformation in the claim.

Use of the terms Machine, Transformation in the M-T examination:

A “machine” is something concrete that consists of parts or certain

devices and the combination of said devices. This includes all the mechanical devices or a combination of mechanic forces and devices to perform some certain function and produce an effect or result. This definition must be interpreted broadly including the electric, electronic, optics, and acoustics fields and other devices that have a function to achieve a determined result.

The “machine” must implement the process, that is, be a fundamental element without which the process could not occur, and not be a secondary element upon which the process operates. The claim must be clear regarding the machine that implements the process and not simply affirm a “process implemented by a machine”. The limitations of the machine must clarify that the use of the machine in the process claimed imposes a significant limitation to the scope of the claim.

The definition of “apparatus” is not very different from that of “machine” and can include a machine or group of machines or of means by which the determined function or specific tax is performed.

An “article” includes a physical object or substance. The physical article or substance can be particular, which means that they can be identified. An article can also be electronic data that represents a physical object or a substance. For the test, the data must be more than an abstract value. Data can be specifically identified when indicating what they represent as per their particular type or nature and/or how or where they were obtained.

“Transformation” of an article means that the “article” has changed to another state or object. Changing to another state or object generally means more than the simple use of an articles or change of location of the article. A different function or use can be evidence that an article has been transformed. Manufacture and compositions of the matter are the result of the transformation of raw materials into something new with a different function or use.

The merely mental processes in which thoughts or basic human actions change are not considered an eligible transformation as eligible matter for a patentability study.

For the data, the mathematics manipulation, on itself alone, is not considered a transformation; but the transformation of electronic data can be considered as such when the nature of the data has been changed in a form that they have a different function or is appropriate for a different application.

A “particular” machine or apparatus or the transformation of a “particular” article means that the method involves a specific machine or article, not any or all possible machines or articles.

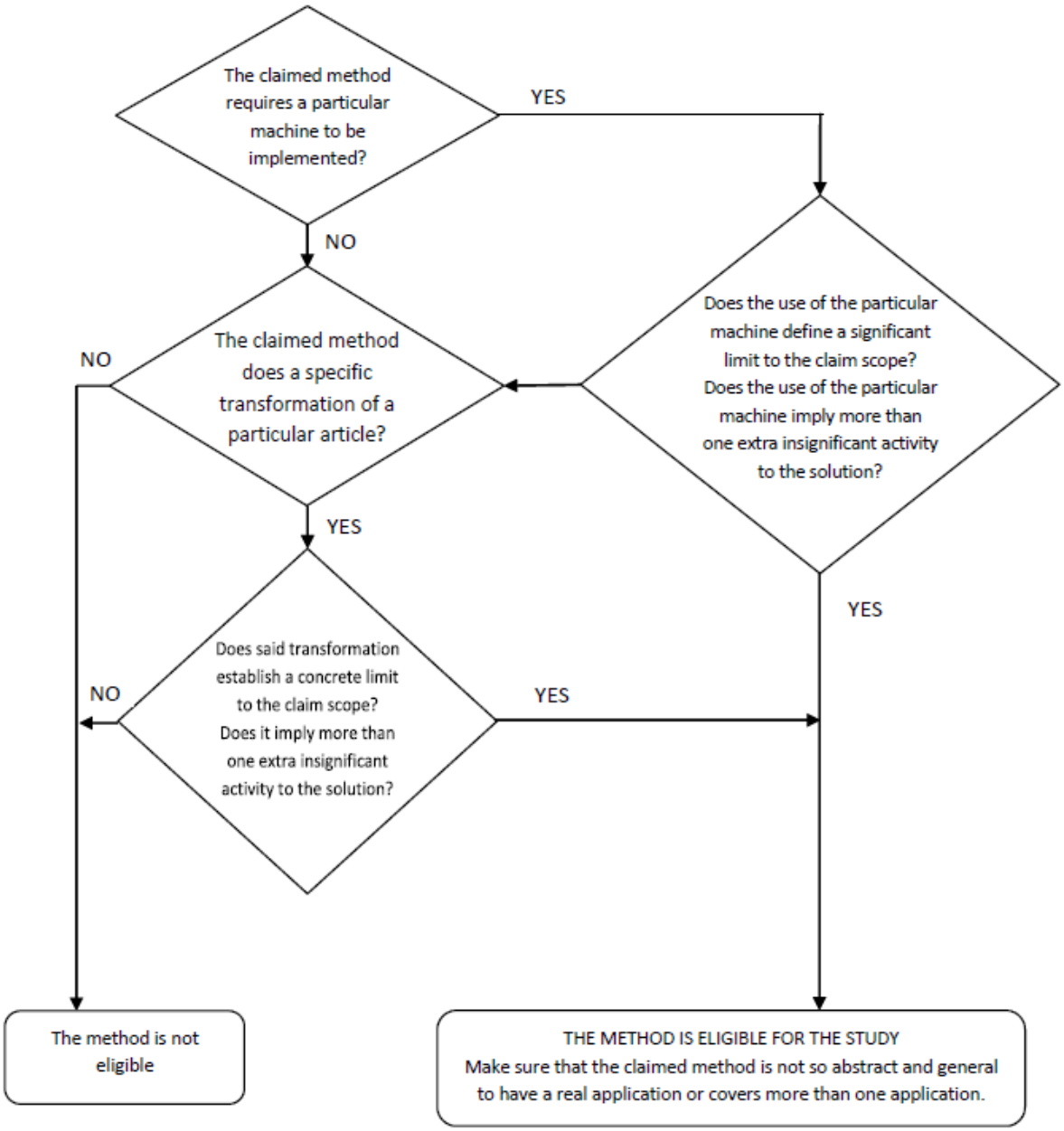
This requires the machine or transformation to set real limits to the procedure claimed, limiting the scope of the claim to a particular practical application.

In the processes implemented in computing systems, the “machine” is frequently described as a general purpose computer. In these cases, the general purpose computer can be “particular” enough when it is programmed to carry out the steps of the process. This programming creates a new machine because a general purpose computer certainly converts into a special purpose computer once it is programmed to perform specific tasks to conform to the instructions of the software application.

To consider a computer as a “particular machine” in the M-T test, the claim must clearly transmit that the equipment is programmed to carry out the steps of said program’s method, thus, be create a special purpose computer, limited to the use of the particular combination of claimed elements (such as, programmed instructions), performing the combination of particular claimed tasks. If the claim is so broad and abstract that the claimed process would be performed covering all the practical applications of non-patentable matter, as a mathematic algorithm, the claim would not pass the test because it would not be particular enough.

A limitation to the “technical field” does not set real limits to the scope of the invention claimed. A limitation to the “technical field” limits to state that the method is for its application in a specific environment, such as “to be applied with a machine” or “to transform an article” which does not establish that the machine implements the method or that the method stages cause the transformation of the article. A limitation to the technical field does not set a significant limit to the claimed invention.

M-T DIAGRAM TO DETERMINE THE MATTER'S ELEGIBILITY TO BE SUBJECT TO THE PROCESSES CATEGORY STUDY



# 7 CHAPTER VII. INTERNATIONAL CLASSIFICATION

In accordance to Art. 49 D 486 to order and classify the patents the International Patent Classification is used; said classification is established under the Strasbourg Agreement of 1971 and its current modifications.

IPC is a hierarchical classification system that covers all the technology sectors and is indispensable to recover information about patents and is checked periodically with the purpose of updating it.

Other IPC important objective are:

- Create an instrument to allow the methodical ordering of the patent documents with the purpose of facilitating access to the technological and legal information contained within;
- Create a medium to disclose selectively the information to all the patent information users;
- Create a medium to look up the state of the art in determined technology sectors;
- Create a medium to prepare industrial property statistics that, in turn, allow the analysis of the evolution of the technological advancement in various sectors.

## 7.1 Contents of the IPC

IPC presents the technical information contained in an invention patent application (for example the claims, description, and drawings) that contribute to the state of the art.

When a technical object of a patent application must be classified, complete symbols of the IPC must be assigned to it so that it expresses all the new and inventive technical information that has been disclosed in the patent application. To complete the information of the invention, it is appropriate to classify the additional information that, although it might not contribute to the state of the art, maybe useful for the search. This information is identified using indexation codes and can correspond to components of a composition or components of a process, characteristics of use or application.

The classification system comprises the following subdivisions: 8 sections, 120 classes, 628 subclasses, and almost 69,000 groups (from which approximately 10% are the “main groups” and the rest “subgroups”).

The sections comprised therein are:

A. Human necessities

B. Performing operations; Transporting

C. Chemistry; Metallurgy

D. Textiles; Paper
E. Fixed constructions
F. Mechanical engineering; Lighting; Heating; Weapons; Blasting
G. Physics
H. Electricity

According to the technical field, every invention will be assigned the classification symbols that are appropriate for the respective sections, classes, subclasses, and groups. For example, the compounds, products, and pharmaceutical procedures are classified in sections A and C, in general, A61 and C07, respectively.

Every section has subsections and each section is divided in classes that, in turn, subdivide in subclasses; each subclass divides in groups and the subgroups form from the main groups.

For example, section A, which corresponds to "human necessities", has the following subsections:

- Agriculture
- Foodstuffs; Tobacco
- Personal or domestic articles
- Health; Life savings; Amusements

"Agriculture" subsection comprises class A01 titled "Agriculture; Forestry; Animal husbandry; Hunting; Trapping; Fishing". This class comprises the following subclasses: A01B, A01C, A01D, A01F, A01G, A01H, A01J, A01K, A01L, A01M, A01N.

"Health, Life savings, Amusement" subsection comprises class A61 titled "Medical or veterinary science; Hygiene". This class comprises the following subclasses: A61B, A61C, A61B, A61D, A61F, A61G, A61H, A61J, A61K, A61L, A61M, A61N, A61P, A61Q.

For example, A61F relates with filters implantable into blood vessels; orthopedic, nursing, or contraceptive devices; treatment or protection of eyes or ears; bandages, dressings or absorbent pads.

A61K relates with preparations for medical, dental, or toilet purposes.

A61P comprises specific therapeutic activity of chemical compounds or medicinal preparations.

A91Q comprises specific use of cosmetics or similar toilet preparations.

In turn, subclasses comprise groups, and these contain specific subgroups; for example, subclass A61K includes the following main groups:

- Preparations for dentistry: 6/00
- Cosmetics or similar toilet preparations: 8/00
- Medicinal preparations

O Characterized by special physical form: 9/00
O Containing organic active ingredients: 31/00, 35/00, 36/00, 38/00
O Vaccinations: 39/00, 45/00
O Characterized by non-active ingredients (carriers, inert additives): 47/00
O Containing genetic material (…), gene therapy: 48/00
The following are examples of subgroups of group 9/00: 9/02, suppositories, bases for suppositories; 9/10, dispersions, emulsions; 9/48, preparations in capsules, for example, of gelatin, of chocolate.
The following are examples of subgroups of group 31/00: 31/13, amines; 31/33, heterocyclic compounds.
Subgroups can also have more specific subgroups; for example, group 31/33 of section A has subgroup 31/335 which corresponds to heterocycles having oxygen as the only ring hetero atom; and this subgroup may include more specific heterocycles containing oxygen contained in subgroup 31/35: heterocycles having six-membered rings with one oxygen as the only ring hetero atom.
For example, if you were searching a compound with medicinal activity and that has a pyran ring (it a heterocycle having six-membered rings with one oxygen as the only ring hetero atom) you would have to search in A61K 31/33, A61K 31/35.

**7.2 Classification method**

To classify a patent application, first, you must determine the technical and additional information that constitute the technical object that must be classified.
The technical object must be classified as accurate as possible, as a whole, and not perform separate classification of its parts. However, if any of the components of the technical object contributes with the state of the art, the component makes part of the technical information and, thus, must be classified as well. For example, if a chair is claimed, it will be classified as a whole; and if a device that is part of the chair is claimed, it will also be classified separately.

**7.3 Classification per function or applicability**

**7.3.1 Classification according to its function**

If the technical object is characterized by its intrinsic nature or function, and it is not limited by a particular use field, the object must be classified according to its function.
Example 1: A chemical organic compound characterized by its chemical structure is classified in C07 per its function.

Example 2: A valve characterized by its structure or functional aspects and that do not depend from the fluid that passes through it (e.g. oil) must be classified in F16K.

**7.3.2 Classification according to its applicability**

They must be classified according to their applicability in the following cases:

- If the technical object consists of an object, which is specially adapted for a particular use or purpose

Example 1: Mechanical valve specially adapted to be inserted in the human heart. It must be classified in A61F 2/24, according to its function.

- If the technical object refers to the particular use or application of an object.

Example 2: Filter specially adapted for cigarettes.

The technical object consists of the inclusion of an element to a system.

The incorporation of a leaf spring to the suspension of a wheeled vehicle is classified in B60G 11/02 according to its application. Now then, if it refers also to the element itself, in this case the leaf spring must be classified in the place of the element F16K.

**7.3.3 Classification according to its function and application**

If the technical object relates with the intrinsic nature or function of an object and its use or purpose, or its application for its inclusion into a system, the classification must be done according to its function, as well as its application.

Example 1: a coating composition that consists of its ingredient and use is classified not only in C09D101/00 according to its function, but in C09D5/00 according to its application.

**7.3.4 Classification of special cases**

- When the technical object must be classified according to its function and there is no place in the classification, it must be classified according to its application.
- When the technical object must be classified according to its application and there is no place in the classification, it must be classified according to its function.
- When the technical object must be classified according to its application and function and there is no place in the classification for the function, it must be classified by its application only. When there is no place for its application, it must be classified by its function only.

### 7.3.5 Multiple classifications

If the object of the patent application consists of different categories such as product and process, it must be classifies in both, respectively.

The technical object can have different classifications. If there is no place in the respective classification for the technical object in certain category, it must be classified according to the most appropriate technical object in other category.

If no category in the classification covers the technical object, this must be classified in the main group "00", for matter not found in said group.

### 7.3.6 Classification of specific technical objects

Chemical compounds

When the technical object consists of a chemical compound per se, such as organic or inorganic, etc., it must be classified in section C; when it also consists of a specific use field, it must be classified also in the category that corresponds to its use, if such use means a contribution to the state of the art. For example in the pharmaceutic field, the object can be classified in A61K and A61P, as well.

Chemical compositions

When the object consists of a composition per se, it must be classified in the category according to its chemical composition.

Example: Glass is classified in C03C; the alloys are classified in C22C; the cement in C04B.

If there is no category in the classification, it must be classified according to its use or application.

Compound preparation or treatment

When the object consists of a chemical compound preparation or treatment, it must be classified in accordance to the preparation or treatment process of the corresponding compound.

When the resulting compound of the preparation process is new, as well, the compound must also be classified. The object related with the general preparation or treatment process of a number of compounds, it must be classified in the category of the process used.

Apparatuses or processes

When the object consists of an apparatus, it must be considered in the section of the apparatuses; if that section does not exist, the apparatus must be classifies in the section related with the process performed with that apparatus.

When the object consists of a process to manufacture or treat products, it must be classified in the section related with the process performed.

When said section does not exist, it must be classified in the section related to the apparatus that performs the process. If there is no category for the apparatus that performs the process, it must be classified in the part concerning to the product.

Manufacturing of products

When the object consists of a product, it must be classified in the section related with the product. If no category exists for the product itself, it must be classified in the appropriate section according to the product's function. If there is no category to classify the function, the classification must be done by its use.

Multiple stage processes, industry plants

When the object consists of a multiple stage process or an industry plant that consist of a combination of process stages or apparatuses, respectively, it must be classified as a whole, for example, in the part provided for said combination (e.g. subclass B09B). If there is no category in the classification, it must be classified in the section that corresponds to the product obtained from the process or the plant. When the object comprises a combination element, too, for example, a machine of the plant, the element must be classified separately.

Elements, structural plants

When the object consists of structural elements or parts of a product or apparatus, the following must be taken into account:

Elements or parts applicable only to, or specially adapted to a class of products or apparatuses must be classified in adequate sections for the elements or parts of the products or apparatuses. If said sections do not exist, these elements or parts must be classified in the appropriate parts for the products or apparatuses.

Elements or parts applicable to more than one of the different classes of products or apparatuses, they must be classified in the adequate sections of the elements or parts of more general nature. If said sections do not exist, these elements or parts must be classified according to all the classes of products or apparatuses to which they explicitly apply.

General chemical formula

The general formulae are often used to express one or more types of compounds where at least one group of the formula is variable, e.g. Markush.

When a large number of compounds are within the scope of the general formula, although they could be classified separately within many categories of the classification, only the most useful chemical compound for the search must be classified.

If the chemical compound is specifically using a general formula, the procedure below must be followed:

Stage 1: Every completely identified compound that is new and has inventive step is classified. A compound is considered as "completely identified" when:

- The structure is given by the exact chemical name or formula, or it can be inferred from its preparation of specified reagents and
- The compound is characterized by a physical property, for example a fusion point, or its preparation is described in an example giving practical elements.

Compounds identified from their empiric formulation are deemed not to have been completely identified.

Stage 2: If unidentified compounds are disclosed, the general formula must be classified in more specific groups that cover all or most of the potential executions. The classification of the general formula must be limited to just one group or to a very small number of groups.

Stage 3: In addition to the classification in accordance to stages 1 and 2, the classification can be done when other compounds that are within the scope of the general formula are important.

**7.3.7 Combination libraries**

Collections made by several chemical compounds, biologic entities, or other substances can be filed in the form of "Libraries".

"Libraries" as a whole can be classified in an appropriate group of subclass C40B. At the same time, individual members, which are completely identified, must be classified in the more specific category; for example, the nucleotide library as a whole must be classified in an appropriate group of subclass C40B. Also, the completely identified nucleotide, must be classified in the appropriate place of section C. Other subclasses in which the combination libraries can be classified are A61K, C07C, and A01N.

For further information about IPC, please visit

http://www.wipo.int/classifications/ipc/en/

http://www.wipo.int/classifications/ipc/en/ITsupport/Version20090101/index.html

## 8 CHAPTER VIII: INTERNATIONAL SYSTEM OF UNITS (SI)

The International System of Units (SI) is the coherent system of units adopted and recommended by the General Conference on Weights and Measures (CGPM).

Nomenclature, definitions, and symbols of the International System units and the recommendations to use the prefixes are collected by the Colombian Technical Standard 1000.

Following, you will find a summary of them and some recommendations about their use. Unit of measure: particular Magnitude defined and adopted as convention with which the other magnitudes of the same nature are compared to express quantitatively their relation with this magnitude.

a. Base or fundamental units:

| **Magnitude** | **Unit** | **Symbol** |
|---|---|---|
| Length | Meter | m |
| Mass | Kilogram | Kg |
| Time | Second | s |
| Electric intensity | Ampere | A |
| Thermodynamic | Kelvin | K |
| Light intensity | Candela | cd |
| Quantity of substance | mole | mol |

b. Derived units (examples)

| **Magnitude** | **Unit** | **Symbol** |
|---|---|---|
| Surface | Square meter | $m^2$ |
| Volume | Cubic meter | $m^3$ |
| Mass density (density) | Kilogram per cubic meter | $kg/m^3$ |
| Linear velocity (speed) | Meters per second | m/s |
| Angular velocity | Radians per second | rad/s |
| Acceleration | Meters per second squared | $m/s^2$ |
| Specific volume | Cubic meters per kilogram | m3/kg |
| Refractive index | (the number) one | 1 |
| Angular acceleration | Radian per second squared | $rad/s^2$ |
| Frequency | Hertz | Hz |
| Force | newton | N |
| Pressure | Pascal | Pa |
| Energy, work, amount of heat | Joule | J |
| Power, flow of energy | Watt | W |
| Amount of electricity, electric charge | Coulomb | C |
| Electric tension | Volt | V |
| Electric capacitance | Farad | F |

| | | |
|---|---|---|
| Electrical resistance | Ohm | Ω |
| Luminous flux | Lumen | lm |
| Illuminance | lux | lx |

c.Supplementary units

| **Magnitude** | **Unit** | **Symbol** |
|---|---|---|
| Angular measure | Radian | rad |
| Solid angle | Steradian | sr |

d. Accepted units that do not belong to the SI

| **Magnitude** | **Unit** | **Symbol** | **Value in SI units** |
|---|---|---|---|
| Mass | Ton | t | 1t = 1,000 kg |
| Time | Minute | min | 1 min = 60 seconds |
| | Hour | h | 1 h = 60 minutes = 3 600 s |
| | Day | d | 1 d = 24 h = 86 400 s |
| Temperature | Celsius degrees | °C | °C = K - 273.15<br>K = °C + 273.15 |
| Angular measure | Degrees | ° | 1° = (1/180)rad |
| Minute | | ' | 1′ = (1/60)° = (1/10 800)rad |
| Second | | " | 1″=(1/60)′=(1/648 000)rad |
| Volume | Litre | L or l | 1 l = 1 $dm^3$ |

e. Prefixes of the SI

| **Name** | **Symbol** | **Factor** | **$1{,}000^n$** |
|---|---|---|---|
| yotta | Y | $10^{24}$ | $1000^8$ |
| yocto | y | $10^{-24}$ | $1000^{-8}$ |
| zetta | Z | $10^{21}$ | $1000^7$ |
| zepto | z | $10^{-21}$ | $1000^{-7}$ |
| exa | E | $10^{18}$ | $1000^6$ |
| atto | a | $10^{-18}$ | $1000^{-6}$ |
| peta | P | $10^{15}$ | $1000^5$ |
| femto | f | $10^{-15}$ | $1000^{-5}$ |
| tera | T | $10^{12}$ | $1000^4$ |
| pico | p | $10^{-12}$ | $1000^{-4}$ |
| giga | G | $10^9$ | $1000^3$ |
| nano | n | $10^{-9}$ | $1000^{-3}$ |
| Mega | M | $10^6$ | $1000^2$ |
| micro | m | $10^{-6}$ | $1000^{-2}$ |
| Kilo | k | $10^3$ | $1000^1$ |
| mili | m | $10^{-3}$ | $1000^{-1}$ |
| Hector | h | $10^2$ | $1000^{2/3}$ |

| | | | |
|---|---|---|---|
| centi | c | $10^{-2}$ | $1000^{-2/3}$ |
| deca | da | $10^{1}$ | $1000^{1/3}$ |
| deci | d | $10^{-1}$ | $1000^{-1/3}$ |

f. Definition of the units

f.1. Length: (meter – m)
The meter is the length of the path travelled by light in vacuum during a time interval of 1/299 792 458 of a second. (17th CGPM of 1983)

f.2. Time: (second – s)
The second is the duration of 9 192 631 770 periods of the radiation corresponding to the transition between the two hyperfine levels of the ground state of the cesium 133 atom. (13th CGPM of 1967, resolution 1)
It is realized by tuning an oscillator to the resonance frequency of the atoms when they pass through magnetic fields and a resonant cavity towards a detector.

f.3. Mass: (kilogram – kg)
The kilogram is the mass of the platinum-iridium prototype, accepted by the General Conference of Weights and Measures in 1889 and deposited in the Pavillon de Breteuil in Sevres (1st and 3rd CGPM of 1889 and 1901)

f.4. Temperature: (kelvin – K)
The kelvin, unit of thermodynamic temperature, is equal to the fraction 1⁄273.16 of the thermodynamic temperature of the triple point of water (exactly 0.01 °C or 32.018 °F). A temperature interval can be expressed in Celsius degrees (°C) (13th CGPM of 1967, resolution 4)
Triple point cell of water: the triple point cell of water –a glass cylinder that contains pure water, sealed at a water steam pressure of 611.657 Pa– is used to reproduce the thermodynamic temperature of the triple point of water. When the cell cools down until it forms an ice layer around the deposit, the temperature on the separation surface of the solid, liquid, and gas state is 273.16 K or 0.01 °C.

f.5. Luminous intensity: (candela – cd)
Luminous intensity is a measure of the wavelength-weighted power emitted by a light source in a particular direction; such source emits monochromatic green light with a frequency of 540 THz, and that has a

radiant intensity of 1/683 watts per steradian in the specified direction (16th CGPM of 1979, resolution 3)

f.6. Electric current: (ampere – A)
The ampere is that constant current which, if maintained in two straight parallel conductors of infinite length, of negligible circular cross section, and placed 1 meter apart in vacuum, would produce between these conductors a force equal to 2 x 10-7 newton per meter of length. (9th CGPM of 1948, resolution 2)

f.7. Amount of substance: (mole – mol)
The amount of any substance that contains as many elementary entities (e.g., atoms, molecules, ions, electrons) as there are atoms in 12 grams of pure carbon-12 (14th CGPM, resolution 3)

g. General rules to use SI
- Unit symbols are not followed by a period unless at the end of a sentence. Example: kg, dm, mg.
- If for some reason the name of a unit is more appropriate than the unit symbol, the name of the unit should be spelled out in full, except in those cases in which there is no risk of confusion when writing the symbol alone.
- Unit symbols are unaltered in the plural. Example: one kilogram = 1 kg; five kilograms = 5 kg.
- It is not permissible to use abbreviations for the unit symbols or names. There are symbols, not abbreviations. Example: grs does not correspond to grams; g does.
- Plural unit names are used when they are required by the rules of the English grammar. Example: meter / meters; second / seconds
- SI prefixes and their symbols will be used to form the names and symbols of multiples or submultiples of the unit concerned. Example: centimeter = cm.
- A combination of names and symbols when expressing the name of a derived unit is not permitted. Example: Not this: meter/s; but this: m/s or meter per second.

h. Decimal sign or marker
The reasons why the comma was chosen as the sign or marker to separate decimal are a group or simple and somewhat humble reasons in their individual conception. However, all of them as a whole explain why the comma was chosen as the single punctuation mark when writing numbers:

- BIPM (International Bureau of Weights and Measures) in the preface of its publication "Le Systeme International d'Unites", 7th Edition, 1998 states that the CIPM (International Committee for Weights and Measures) decided in 1997 that the dot is the accepted decimal sign or marker for use in texts in English; the other cases use the comma as the decimal sign or marker.
- The comma is accepted by the International Organization for Standardization – ISO (that is, in 90 countries worldwide) as the only punctuation mark to write numbers.
- The importance of the comma to separate decimals is huge. This is due to the essence of the Metric System; therefore, it must be visible and should not be lost during the enhancement or reduction process of documents.
- Comma is more easily identified and recognized than dot.
- As it has its own shape, the comma requires the writer the intention to write it down. Conversely, the period can be accidental or the result of a distraction.
- Fraud is facilitated by the dot because it can be converted into a comma, but not otherwise.
- In mathematics, physics and, in general, science and engineering fields, the dot is used as the sign for the multiplication of numbers or values. This could lead to an error or cause confusion; the same punctuation mark or sign should not be used for two different purposes.
- In our common language, the comma separates two parts of the same clause or phrase, while the dot or period pinpoints a complete sentence. Consequently, it is more logic to use the comma as the decimal marker of a same amount or value.
- It is a strict rule that the decimal marker always have, at least, one digit one the right and on the left. However, countries in which the dot is the decimal marker, expressions such as .25 are usual instead of using the correct form 0.25. This incorrect form can have serious consequences; for example, if a doctor prescribes .25 mg and does not mark the dot firmly, the nurse or pharmacist can easily read and administer or prepare 25 mg which is 100 times higher than what was prescribed and can lead to death. If the doctor had prescribed 0.25 mg, this would not have happened, even if the dot had not been clearly written; in such case the reading would be 0 25 mg which immediately and naturally leads to understand that the decimal marker has not been written.

In the countries that adopt the metric system and use the comma as the decimal sign, the previous case is not likely to occur because the

comma is more visible and can be identified easily. And, even though the writer would be willing to write ‘,25’ because this is a unusual form, it is evident the need to include a zero before the comma.
- One of the most important reasons to accept the International System of Units - SI, which is nothing more than a modern revision of the Metric System, is the idea of facilitating trade and sharing knowledge and reports in a metric world. The comma is used as the decimal sign or marker in the whole continental Europe and almost all South America. Adopting the comma, which is a practice accepted worldwide, allows us to benefit from the global exchange of science and experience, without confusions or doubts.

i. Use of unit names
- The full names of SI units are written in lower case, except for Celsius degrees, unless they start a sentence/phrase or after a period.

| **Correct** | **Incorrect** |
|---|---|
| meter | Meter |
| kilogram | Kilogram |
| newton | Newton |
| watt | Watt |

- Units, multiples, and submultiples can only be designated with their full names or their corresponding well-known international symbols. The use of any other is not permitted.

| **Correct** | **Incorrect** |
|---|---|
| m (meter) | mts, mt, Mt, M |
| Kg (kilogram) | kgs, kgr, kilo, KG |
| g (gram) | gr, grs, Grs, g. |
| L o l (litre) | lts, lt, Lt |
| K (kelvin) | k |
| $cm^3$ (cubic centimeter) | cc, cmc, c.c. |
| km/h (kilometer/hour) | kph, kmh, kmxh |

- The units which names are of the scientists, they must not be translated; they must be used as in the language of origin.

| **Correct** | **Incorrect** |
|---|---|
| newton | Niutonio |
| sievert | sievertio |
| joule | Julio |
| ampere | amperio |

j. Rules to use the symbols

- Each unit and prefix have one single symbol that cannot be altered by any means. No abbreviations are accepted. Example:

| **Correct** | **Incorrect** |
|---|---|
| 10 $cm^3$ | 10 cc |
| 30 kg | 30 kgrs. |
| 5 m | 5 mts. |
| 10 t | 10 TON |

- All the symbols of the SI units are written in lowercase letters of the Latin alphabet, except ohm (Ω) which uses the Greek letter omega in uppercase; but those that are used after the name of the scientists must be written in uppercase. Example:

| **Correct** | **Incorrect** |
|---|---|
| kg | kilogram |
| A | ampere |
| cd | candela |
| Ω | ohm |

- The symbols are not pluralized; they are always written in singular regardless of the numeric values accompanying them. The symbol represents the unit. Example 5 kg – 255 m.
- No punctuation mark must be written after a symbol unless the punctuation rule requires it; a space must be left between the symbol and the punctuation mark. Example: (…) which length is 7.1 m. Which is (…)
- Symbols are written to the right of the numeric values separated by a blank space. However, this space will not exist in case of the sexagesimal units of an angle. For example: 10 A, 100 °C, 270 K, 30 m, 40°30’20”.
- Every numeric value must be expressed with its unit, even when it repeats or the tolerance is specified. Example: 30 m + 0.1 m; (…) from 14 h to 18 h (…)

k. Prefixes

- All the names of SI prefixes are written in lowercase.

Example:

kilo
mega
mili
micro

- Symbols of prefixes to form multiples are written using Latin uppercase letters, except kilo which is written in lowercase.

Example:
Exa E
giga G
mega M
kilo k
- Symbols of prefixes to form submultiples are written using Latin lowercase letters, except for the symbol of the prefix 'micro' that uses the Greek letter mu in lowercase (μ).
Example:
mili m
micro μ
nano n
pico p

- Multiples and submultiples of the units of measure are formed by placing the names or symbols of the prefixes to the word gram.
Example:
kilometer km
mili ampere mA
megavolt MV

The exception is the mass unit
- Mass measuring multiples and submultiples are formed by writing the names or symbols of the prefix to the word 'gram'.
Example:
Mg Megagram
kg kilogram (base unit)
g gram
mg miligram
$\mu$g microgram
- Two or more prefixes will not be used before the symbol or name of the measuring unit.
Example:

| Correct | Incorrect |
| --- | --- |
| hm (hectometer) | dkm (decikilometer) |
| na (nanoampere) | mm A (milimicroampere) |
| MW (megawatt) | kkW (kilokilowatt) |

- Multiples and submultiples of the measuring units must be generally chosen so that the numeric values be between 1 and 1000.
Example:

Recommended Not recommended
750 km 750 000 m
- Prefixes hector, deca, deci, and centi are allowed when using area units (m2) or volume units (m3). Other physical magnitudes must use only the preferred prefixes.

l. Writing of numbers
- Numbers with many digits must be grouped by three, from the comma, both for the whole number and the decimal part. Each group must be separated using a blank space the same size or smaller than the size of a digit but larger than the space left normally between the digits.
Example: 1 362 743.038 29
- To express large numbers in order, follow the rule 3n (powers of ten in multiples of three), which establishes the following equivalences:
Example:
1 million 106
1 billion 1012
1 trillion 1018
1 quadrillion 1024
1 quintillion 1030
- The first digit to the left of the decimal marker has the value of the unit in which the number is expressed.
Example:
34.5 m (the digit 4 expresses meters)
0.25 N (the digit 0 expresses newtons)
1.85 m (the digit 1 expresses meters)
220 V (the digit 0 expresses volts)
The symbols of the unit in which the number is expressed must be written after the complete numeric value and be separated using a space.
- If a symbol that contains a prefix is affected by an exponent, it affects the whole unit.
Example:
1 cm3 = (0.01 m) 2 = 0.0001 m2
10 s = (10 s) 1 = 10 s

m. Representation of time
The numeric representation of time will use the following Arabic digits: 0, 1, 2. 3, 4, 5, 6, 7, 8, and 9; and the following symbols will be used: h (hour), min (minute), s (second).
The time will be expressed using two digits to express the numeric

values of the hours, minutes, and seconds, the symbols of these units are separated with blank spaces, and the values following this order: hour minute second

Example:

12 h 05 min 30 s

00 h 30 min 05 s

18 h 00 min 45 s

Incorrect forms to express time

3 pm

10 and 15

6 am

20 to 11

6 in the afternoon

VI hours

n. Representation of dates using numbers

The numeric representation of dates will use the following Arabic digits: 0, 1, 2. 3, 4, 5, 6, 7, 8, and 9; the years will be expressed using the four digits and are written as a whole. Two digits are acceptable when there is no risk of confusion.

Example:

1989 or 89

1990 or 90

Two digits will be used to express days and months.

This is the correct order to express a full date:

Year month day; a hyphen will be used to separate them.