



Licks
ATTORNEYS

Examination Guidelines for Patent Applications

Block II - Patentability

This text is an integral part of the Patent Application Examination Guidelines setting out the current understanding of the BRPTO on patentability. Other inherent exam topics are listed and discussed in the general guidelines.

Patent Division - March 16, 2015

FEDERAL CIVIL SERVICE

MINISTRY OF DEVELOPMENT, INDUSTRY AND FOREIGN TRADE

BRAZILIAN PATENT AND TRADEMARK OFFICE

EXAMINATION GUIDELINES FOR PATENT APPLICATIONS

BLOCK II

PATENTABILITY

Revision of Guidelines for Patent Applications Examination

PATENT DIVISION – MARCH 16, 2015

SUMMARY

CONTENTS OF PATENT APPLICATION	7
CHAPTER I. INVENTIONS	7
INTRODUCTION	7
BASIC REQUIREMENTS	7
MATTERS THAT ARE NOT CONSIDERED INVENTION.....	7
§I. DISCOVERIES, SCIENTIFIC THEORIES AND MATHEMATICAL METHODS - ITEM I OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE	7
DISCOVERIES	7
SCIENTIFIC THEORIES.....	8
MATHEMATICAL METHODS.....	8
§II. PURELY ABSTRACT CONCEPTS - ITEM II OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE.....	8
§III. COMMERCIAL, ACCOUNTING, FINANCIAL, EDUCATIONAL, ADVERTISING, LOTTERY OR FISCAL NATURE	8
SCHEMES, PLANS, PRINCIPLES OR METHODS – ITEM III OF ARTICLE 10 OF BRAZILIAN IP STATUTE.....	8
§IV. LITERARY, ARCHITECTURAL, ARTISTIC AND SCIENTIFIC WORKS OR ANY AESTHETIC CREATION - ITEM IV OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE.....	9
§V. COMPUTER PROGRAM PER SE - ITEM V OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE.....	10
§VI. PRESENTATION OF INFORMATION - ITEM VI OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE	10
§VII. GAME RULES - ITEM VII OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE.....	11
§VIII. OPERATIVE OR SURGICAL, AND THERAPEUTIC OR DIAGNOSTIC METHODS AND TECHNIQUES FOR APPLICATION IN THE ANIMAL OR HUMAN BODY - ITEM VIII OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE ...	11
THERAPEUTIC METHOD	11
OPERATIVE OR SURGICAL METHOD.....	12
DIAGNOSTIC METHOD	13
§IX. NATURAL LIVING BEINGS, IN WHOLE OR IN PART, AND BIOLOGICAL MATERIAL, INCLUDING THE GENOME OR GERM PLASMA OF ANY NATURAL LIVING BEING, WHEN FOUND IN NATURE OR ISOLATED THEREFROM, AND NATURAL BIOLOGICAL PROCESSES - ITEM IX OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE	14
NON-PATENTABLE INVENTIONS - ARTICLE 18 OF THE BRAZILIAN IP STATUTE	14
§I. WHATEVER IS CONTRARY TO MORALS, GOOD CUSTOMS AND PUBLIC HEALTH, ORDER AND SECURITY - ITEM I OF ARTICLE 18 OF THE BRAZILIAN IP STATUTE	14
§II. SUBSTANCES, MATTER, MIXTURES, ELEMENTS OR PRODUCTS OF ANY KIND, AS WELL AS THE MODIFICATION OF THEIR PHYSICAL- CHEMICAL PROPERTIES AND THE RESPECTIVE PROCESSES OF OBTAINING OR MODIFYING THEM, WHEN THEY RESULT FROM THE TRANSFORMATION OF THE ATOMIC NUCLEUS - ITEM I OF ARTICLE 18 OF THE BRAZILIAN IP STATUTE	15
§III. LIVING BEINGS, IN WHOLE OR IN PART, EXCEPT TRANSGENIC MICRO-ORGANISMS MEETING THE THREE PATENTABILITY REQUIREMENTS - NOVELTY, INVENTIVE ACTIVITY AND INDUSTRIAL APPLICATION – PROVIDED FOR IN ARTICLE 8 AND WHICH ARE NOT MERE DISCOVERIES - ITEM III OF ARTICLE 18 OF THE BRAZILIAN IP STATUTE	16

CHAPTER II. INDUSTRIAL APPLICATION	17
CHAPTER III. STATE OF THE ART	17
DEFINITION AND GENERAL CONCEPTS	17
RELEVANT DATE FOR SEARCHING PRIOR ART	18
SUFFICIENCY OF DISCLOSURE	18
DOCUMENTS IN UNOFFICIAL LANGUAGE.....	18
PRIOR ART DOCUMENTS UNPUBLISHED ON THE RELEVANT DATE OF THE APPLICATION UNDER EXAMINATION (ARTICLE 11 §2 OF THE BRAZILIAN IP STATUTE)	19
MEANS OF DISCLOSURE.....	19
§I. PUBLISHED DOCUMENTS.....	20
§II. ORAL DISCLOSURE.....	20
§III. DISCLOSURE BY USE.....	21
MATERIAL FOUND ON THE INTERNET USED AS PRIOR ART	21
§I. ASSIGNMENT OF PUBLICATION DATE	22
§II. TECHNICAL JOURNALS.....	23
§III. OTHER PUBLICATIONS.....	23
§IV. TECHNICAL DETAILS AND GENERAL COMMENTS.....	24
CROSS-REFERENCES BETWEEN THE STATE OF THE ART DOCUMENTS	24
ERRORS IN STATE OF THE ART DOCUMENTS.....	24
GRACE PERIOD - ARTICLE 12 OF THE BRAZILIAN IP STATUTE.....	25
CHAPTER IV. NOVELTY	25
SPECIFIC TERM AND GENERAL TERM	27
NUMERICAL VALUE AND NUMERICAL RANGE	27
CLAIMS OF A PRODUCT DEFINED BY CHARACTERISTICS OF PERFORMANCE, PARAMETERS, USE OR MANUFACTURING PROCESS.....	28
CLAIMS OF SECOND NON-MEDICAL USE.....	30
SELECTION PATENTS	30
CHAPTER V. INVENTIVE STEP	31

CONCEPT.....	31
STATE OF THE ART	31
PERSON SKILLED IN THE ART	31
ASSESSMENT OF INVENTIVE STEP.....	32
§I. OVERVIEW.....	32
§II. STEPS FOR EXAMINING AN INVENTIVE STEP.....	32
DETERMINING THE CLOSEST STATE OF THE ART	32
DETERMINING THE DIFFERENT CHARACTERISTICS OF THE INVENTION AND THE TECHNICAL PROBLEM SOLVED BY THE INVENTION	33
DETERMINING WHETHER THE INVENTION IS OBVIOUS FOR THE PERSON SKILLED IN THE ART	34
§III. COMBINATION OF STATE OF THE ART DOCUMENTS	34
SPECIFIC SITUATIONS IN ASSESSING INVENTIVE STEP	34
§I. INVENTION THAT OPENS UP A NEW FIELD	34
§II. INVENTION BY COMBINATION	35
OBVIOUS COMBINATION	35
NON-OBVIOUS COMBINATION	35
§III. INVENTION BY SELECTION	36
OBVIOUS SELECTION	36
NON-OBVIOUS SELECTION.....	37
§IV. INVENTION BY ANALOGY OF A TECHNICAL FIELD.....	37
§V. INVENTION OF A NEW USE (NON-MEDICAL) OF A KNOWN PRODUCT.....	38
§VI. INVENTION BY ALTERATION OF ELEMENTS.....	39
INVENTION BY ALTERATION OF RELATIONS BETWEEN ELEMENTS	39
INVENTION BY SUBSTITUTION ELEMENTS	39
INVENTION BY OMISSION ELEMENTS	40
SECONDARY FACTORS TO BE CONSIDERED UPON EXAMINING AN INVENTIVE STEP.....	40
§I. SOLUTION OF A LONG-KNOWN BUT UNSOLVED TECHNICAL PROBLEM	40
§II. OVERCOMING PRECONCEPTION OR TECHNICAL BARRIER.....	41
§III. ACHIEVING COMMERCIAL SUCCESS	41
§IV. WINNING AWARDS	41
§V. HOW THE INVENTION IS CREATED	41
CHAPTER VI. MARKUSH FORMULAS	41
INTRODUCTION.....	41
NOVELTY.....	42
INVENTIVE STEP.....	42

SUFFICIENCY OF DISCLOSURE	43
SUPPORT, CLARITY AND PRECISION OF THE CLAIMS	43
CHAPTER VII. COMPOSITIONS	44
NOVELTY	44
CLARITY AND ACCURACY.....	45
§I. REQUIREMENT FOR QUALITATIVE/QUANTITATIVE DEFINITIONS	45
TYPES OF COMPOSITION.....	45
§I. COMPOSITIONS DEFINED SOLELY FOR THEIR USE, ADMINISTRATION METHOD OR ACTION MECHANISM	45
§II. KIT INCLUDING COMPOSITIONS.....	46
§III. PRODUCT INCLUDING COMPOSITIONS CHARACTERIZED BY THEIR PHYSICAL SHAPE AND/OR FORM OF APPLICATION.....	46
§IV. COMBINATION OF ACTIVE INGREDIENTS.....	47
SYNERGIC (OR SUPRA-ADDITIVE) EFFECT	47

CONTENTS OF PATENT APPLICATION

CHAPTER I. INVENTIONS

INTRODUCTION

1.01 An invention must be of technical character and be feasible in any technological field. It is necessary for the invention to be included in a technical sector; solves technical problems, consisting of the solution for such problems and has a technical effect. It is therefore necessary for the application to show evidence of the technical nature of the problem to be solved, of the proposed solution and of the achieved effects.

BASIC REQUIREMENTS

1.02 The three requirements for patentability of an invention are as follows:

- i. industrial application;
- ii. novelty; and
- iii. inventive step.

These requirements must be checked in the above order. If the application fails to present one of the requirements, it is not necessary to examine the others. There may be cases where the examiner deems it necessary to assess the other requirements, in order to deal exhaustively the exam of the invention as a whole.

The examiner must identify if the claimed matter, considered as a whole, fits articles 10 and 18 of the Industrial Property Statute (Brazilian IP Statute), according to the instructions given in the items on “matters that are not considered an invention” and of “non-patentable inventions” of these Guidelines.

MATTERS THAT ARE NOT CONSIDERED INVENTION

§I. DISCOVERIES, SCIENTIFIC THEORIES AND MATHEMATICAL METHODS - ITEM I OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

DISCOVERIES

1.03 If a new property of a product is found, this property is considered a mere discovery that is not considered an invention.

1.04 A product that presents that property, giving it a practical use can be considered an invention.

Example¹: *Discovery that a known material in particular is fit to withstand a mechanical shock is not considered an invention.*

Example²: *A railway crosstie of this material could be considered an invention.*

1.05 A product found in nature is not considered an invention, since it is a discovery, even though separate from it.

Example: *Natural minerals and chemicals elements*

1.06 For questions involving biological products and processes found in nature, see the provision in item IX of article 10 of Brazilian IP Statute.

SCIENTIFIC THEORIES

1.07 These are a more general form of discoveries, and the same principle mentioned in the item on discoveries of this guideline applies.

Example: *The physical theory of semi-conductors is not considered an invention. However, new semiconductor devices and processes for their manufacture may be considered an invention.*

MATHEMATICAL METHODS

1.08 Mathematical methods are particular examples of the principle that intellectual or purely abstract methods are not considered an invention, since they do not comprise the solution of a technical problem.

Example¹: *A fast dividing method would not be considered an invention, but a calculator built to do this may be considered an invention.*

Example²: *A method to develop electric filters, although referring to a mathematical equation, is considered an invention, since it is the solution of a technical problem.*

Example³: *A method to encrypt/decipher electronic communications may be considered a technical method, even if essentially based on a mathematical method.*

§II. PURELY ABSTRACT CONCEPTS - ITEM II OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.09 Everything that exists only at the level of ideas, with no feasible practical implementation, constitutes idea, a purely abstract concept and, consequently, is not considered an invention under article 10 item II of the Brazilian IP Statute. As purely abstract concepts, nor are they descriptiveness. Methods referring to a sequence of actions to solve a technical problem are not understood as pure abstractions. Although the application is sufficiently described, the framework as a purely abstract concept will not necessarily be removed. Consider the idea of an invisible car. As a non-achievable idea by person skilled in the art, it is a purely abstract concept and, therefore, is not considered an invention. If the inventor describes a method that is able to implement such a vehicle, this achievement may be the object of a patent.

§III. COMMERCIAL, ACCOUNTING, FINANCIAL, EDUCATIONAL, ADVERTISING, LOTTERY OR FISCAL NATURE

SCHEMES, PLANS, PRINCIPLES OR METHODS – ITEM III OF ARTICLE 10 OF BRAZILIAN IP STATUTE

1.10 Item III of article 10 of the Brazilian IP Statute determines that commercial, accounting, financial, educational, advertising, lottery or inspection schemes, plans, principles or methods, are not considered an invention. The fact that these methods are implemented by computer program is irrelevant for the framework of such a method in article 10, III of the Brazilian IP Statute.

Example: Creations provided in item III of article 10 of the Brazilian IP Statute include:

- i. market analysis, auctions, consortiums, incentive programs, point of sale (POS) methods, funds transfer – using a banking network or ATM, which includes, amongst its operational steps, exchange calculations and services charges; banking methods, tax processing, insurance, asset analysis, financial analysis; auditing methods, investment planning, retirement plans, medical insurance, online purchase methods; air ticket sales through the Internet, and so on.

1.11 The fact that a method is applied to the financial sector, such as banks, does not necessarily mean it is included as a financial method. It is necessary to evaluate the claimed matter as a whole, if it solves a technical problem.

Example: A method that identifies a bank note by its pattern of images, color and text, is considered an invention, since it is a technical problem, although the method is specifically adapted to a bank note. In this case the technical problem concerns the identification and count of the objects, which does not configure as a financial method.

1.12 A banking machine operating method, characterized by the steps of reading user card, identifying and comparing with a password with the card's data, offers a non-financial technical solution, which is the user authentication. Thus, such a method may be considered an invention. Other solutions referring to communication protocols, encryption applied to bank accounts or conversion of data formats may also be considered an invention.

§IV. LITERARY, ARCHITECTURAL, ARTISTIC AND SCIENTIFIC WORKS OR ANY AESTHETIC CREATION - ITEM IV OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.13 An aesthetic creation by definition is related to an article that presents other non-technical aspects, the appreciation of which is essentially subjective.

Example: A painting or sculpture.

1.14 If, however, the article also has technical characteristics, it may be considered an invention.

Example: A tire-tread.

1.15 The aesthetic effect is not taken into account when assessing an invention, neither in a product nor processing claim.

Example: A claimed book only in terms of the artistic or aesthetic effect of its informational content, layout or its source of lettering, would not be considered an invention, and nor would a painting defined by the aesthetic effect of its subject or color layout or by the artistic style, such as Impressionism, for example.

1.16 Nevertheless, if an aesthetic effect is obtained using a technical structure or other technical means, although the aesthetic creation as such is not considered an invention, the means to obtain it may be.

Example¹: A textile with an attractive appearance, obtained by using a layered structure not previously used for this purpose, may be considered an invention.

Example²: A book defined by a technical characteristic of binding or gluing could be patentable, even if it also presents

an aesthetic effect, just as a painting defined by the type of fabric, or coloring or additives used.

1.17 A process to produce an aesthetic creation can also be considered an invention.

Example¹: *A diamond can have a particular aesthetic form (not consider an invention), produced by a new technical process. In this case the process can be considered an invention.*

Example²: *A new printing technique for a book resulting in a particular layout with an aesthetic effect can be considered an invention, together with the book obtained as a product of that process.*

§V. COMPUTER PROGRAM PER SE - ITEM V OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.18 The computer program as such, addressed in item V of article 10 of the Brazilian IP Statute, refers to the literal elements of creation, such as the object code or source code, understood as an organized set of instructions written in a natural or coded language. As a set of instructions, code or structure, the computer program as such is not considered an invention, and therefore is not an object of protection by patent to be mere an expression of a technical solution, being intrinsically dependent on the programming language.

1.19 The set of instructions in a language, whether in source code or the structure of a source code, even if the instructions are creative, is not considered an invention, even if it provides technical effects.

Example¹: *Alterations to the source code of the program, which bring the benefit of higher speed, smaller memory space, modularity, although technical effects, belong to the scope of the computer program as such.*

Example²: *The computer program as an object open to copyright is not considered an invention, and it is a consequently excluded from patentability.*

Example³: *An industrial creation - process or product associated with the process - implemented by a computer program, which solve a problem found in the technique not solely concerning the way in which this computer program is written, can be considered an invention.*

1.20 It is worth stressing that, if the technical effects are the result of changes in the computer program code and not in the method, the creation is not considered an invention.

§VI. PRESENTATION OF INFORMATION - ITEM VI OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.21 Any creation characterized only by its informational content, such as music, text, image and data, is considered presentation of information and, thus, is not considered an invention.

Example¹: *The presentation of information contained in a medication information leaflet is not considered an invention.*

Example²: *Attributing different colors to different weights used in dumbbells is not considered an invention but rather presentation of information.*

Example³: *The case of disclosing information on panels fixed to the back window of a vehicle, with no particular*

functionality, is presentation of information and, therefore, is not considered an invention.

Example⁴: *Panels fixed to the back window of a vehicle, which are a specific film that preserves the driver's visibility, is a matter considered to be an invention.*

1.22 In the case of the user's graphic interfaces used in computers, the aspects regarding only their informational content are not considered an invention in according to item VI of article 10 of the Brazilian IP Statute.

Example: *The matter raised in a claim that defines a graphic interface dealing with the layout of the icons on the screen, with no technical effect or functionality, is not considered an invention.*

1.23 On the other hand, the method associated with the functional aspects of such interfaces can be considered an invention.

Example: *A claim that addresses a graphic interface that associates personal annotations with excerpts from the document using XML tags can be a technical solution considered an invention.*

§VII. GAME RULES - ITEM VII OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.24 Game rules are not considered an invention by being the solution of a problem not considered as technical, for example, a crossword-solving method. Automation of a game rule, inventive or otherwise, does not change the fact that this is a game rule.

1.25 In game patent applications any references to game rule must be eliminated from the claimed chart, which very often appear mixed with technical descriptions of the patent application. Board games could be patented if they were to present some new layout or format, such as recesses or grooves that would facilitate fixing the pieces, or fit to prevent the board from slipping or for adapting to outdoor use such as the beach, as well as layouts that permit folding the board to pack it in a smaller space, are patentable.

1.26 The line and color layout is not considered an invention applied to the object.

§VIII. OPERATIVE OR SURGICAL, AND THERAPEUTIC OR DIAGNOSTIC METHODS AND TECHNIQUES FOR APPLICATION IN THE ANIMAL OR HUMAN BODY - ITEM VIII OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.27 Pursuant to item VIII of article 10 of Brazilian IP Statute, diagnostic, operative/surgical or therapeutic methods for application in the animal or human body are not considered an invention.

THERAPEUTIC METHOD

1.28 Therapeutic methods are those intended to cure and/or prevent a disease or malfunction of the human or animal body, or relieve symptoms of pain, suffering and discomfort, in order to restore or maintain its normal conditions of health.

1.29 Thus, therapeutic methods adopted in or outside the body are not considered an invention. Anti-ectoparasite treatment is included amongst these methods.

Example: *Lice, methods of laser retina treatment, treating a patient by extracorporeal dialysis or filtering method, in which the filtered blood is returned to the body at the end of the process.*

1.30 The following claim formats are considered therapeutic methods: the treatment of a medical condition Y characterized by the administration of substance X; the use of substance X characterized for treating a medical condition Y.

1.31 Although both the disease prevention and cure are considered therapeutic methods, there should be a direct link between the treatment and condition to be treated or prevented. Accordingly, hygiene methods are not considered therapeutic, although they may result in reducing the incidence of infection. Likewise, purely cosmetic methods are not considered therapeutic. However, if the cosmetic method is directly related to prevention or cure of an disease this method will be regarded as having an associated therapeutic character and, therefore, not considered an invention.

1.32 Treatment methods with no therapeutic character:

Example¹: *Method to increase wool production characterized by administering compound X to sheep;*

Example²: *Human skin hydration method characterized by applying compound Y to the human skin to prevent premature aging of the skin - in this case, there is no indication in the application that the composition and hydration method also can be used to prevent some skin disease.*

1.33 However, there are some cases where the methods can be at the same time therapeutic and non-therapeutic. If the non-therapeutic effect is inseparable from the therapeutic effect, or even if it is only a side effect of the therapy, the matter is not considered an invention. Thus, methods for removing dental plaque, or prevent plaque formation, are considered therapeutic, since that inherent therapeutic effect of removing plaque cannot be separated from the purely cosmetic effect of improving the appearance of the teeth. Likewise, in the case of animal treatments where there is an increase in meat production or another industrial benefit as an inevitable consequence of the cure or prophylaxis of pathology of the animal, it is not possible to dissociate the therapeutic effect.

1.34 On the other hand, body's hair reduction methods can be used for purely aesthetic reasons or for treating hirsutism (i.e. the therapeutic character can be separated, using a negative limitation to exclude hirsutism), and may be eligible for protection.

OPERATIVE OR SURGICAL METHOD

1.35 Any method that requires an operative step, or invasive step in the animal or human body is considered an operative method, with reference to what article 10 (VIII) establishes not to be an invention.

1.36 By definition, operative processes intended to cure diseases are so-called surgical methods or surgery. Surgery can focus on curing diseases or on prophylaxis, such as, for example, if the appendix or tonsils are removed before any related disease appears, and also operative methods that do not have a therapeutic character, such as cosmetic surgery. Likewise, methods defining the insertion or implant of devices using surgical methods are also not considered an invention.

1.37 Moreover, invasive methods such as endoscopy, puncture, injection, excision and catheterization will also be considered operative methods. Likewise, a method for an embryo implant, and artificial insemination in vivo, will be considered an operative method, whatever its purpose.

DIAGNOSTIC METHOD

1.38 The diagnosis is the determination of the nature of a medical condition, generally by investigating its history, etiology and symptoms and by applying tests. The diagnosis per se is an intellectual exercise that is not considered to be an invention.

1.39 The diagnostic method involves a series of steps that lead to identifying a clinical condition, including analysis and interpretation stages of the resulting data. When they are to be applied in the animal or human body, they are not considered an invention pursuant to item VIII of article 10 of the Brazilian IP Statute.

1.40 It is considered a diagnostic method for application in the animal or human body pursuant to item VIII of article 10 of the Brazilian IP Statute, when it meets the following criteria: (i) has direct application in the animal or human body, such as, for example, in the case of determining allergic conditions by a diagnostic examination of the body, or requiring the patient's presence or participation for its interpretation; and (ii) permits the conclusion of the clinical status of the patient, or indicate various probable clinical statuses, only using as a basis the processing, analysis or interpretation of data, information and/or results of clinical tests associated with the patient.

1.41 Some examples of diagnostic methods that are not considered an invention.

Example¹: *A patient's automated diagnostic method characterized by the fact that it comprises the following steps:*

- i. examining the patient to provide at least one first element of a symptom having a relative first degree of importance for the symptom;
- ii. examining the patient to provide at least a second element of a symptom having a relative second degree of importance for the symptom;
- iii. applying the relative degrees of importance for the symptoms, in order to obtain a diagnostic score to conclude a medical condition.

Example²: *Diagnostic method of occlusive diseases in patients, characterized by the fact that it includes:*

- i. establishing separate basic data of size and angle measurements of the markings of facial harmony and values compiled from a group of faces;
- ii. accessing the patient's facial features, finding markings in the facial structures and measuring the size and angle of the patient's face;
- iii. comparing the values of measured markings and angle and value measurements of the patients with corresponding basic data.

1.42 Such a method consists of compiling and establishing standard data about facial measurements, providing and making markings on the patients, and comparing data to reach a diagnosis, being, therefore, applied in the human body and requiring patients for its interpretation.

1.43 On the other hand, in vitro tests performed on blood samples or other tissues taken from the body are, consequently, considered an invention. Moreover, the diagnostic methods may include in vivo and in vitro stages. In such cases, if the claimed method includes technical stages performed in vivo, which are inseparable from the in vitro stage, the method as a whole will be considered as being applied to the body and, therefore, not considered an

invention. Furthermore, the treatment of body tissues, cells or fluids after having been removed from the animal or human body, or methods applied to them, such as in vitro methods, may be eligible for protection. This situation includes methods of measuring enzymes and blood sugar, blood tests, serology tests and so on.

1.44 Also, methods to obtain information from the animal or human body are not considered diagnostic methods, when the collected data are merely an intermediary result that by themselves are not sufficient for a decision or diagnosis.

Example¹: *Methods eligible for protection include methods for obtaining and/or processing X-ray images, magnetic resonance, in addition to processing physiological signs, such as, electrocardiograms and electroencephalograms, to obtain a patients' data.*

§IX. NATURAL LIVING BEINGS, IN WHOLE OR IN PART, AND BIOLOGICAL MATERIAL, INCLUDING THE GENOME OR GERM PLASMA OF ANY NATURAL LIVING BEING, WHEN FOUND IN NATURE OR ISOLATED THEREFROM, AND NATURAL BIOLOGICAL PROCESSES - ITEM IX OF ARTICLE 10 OF THE BRAZILIAN IP STATUTE

1.45 The whole or part of natural living beings and biological materials, found in nature, or even if isolated or produced synthetically that have naturally occurring correspondents indistinguishable from them, will not be considered an invention, pursuant to item IX of article 10 of the Brazilian IP Statute.

1.46 The provision in item IX of article 10 of the Brazilian IP Statute applies to product claims. For process claims, such as processes, methods, uses, applications and so on, the provision in item IX of article 10 of the Brazilian IP Statute refers solely to natural biological processes, stating that they are not considered invention. When the claimed process involves the whole or part of natural living beings and biological materials found in nature, including the genome or germplasm, but does not consist of a natural biological process, there is no impediment for its patentability pursuant to item IX of article 10 of the Brazilian IP Statute. Accordingly, the process using a natural product represents the result of a human intervention and is considered invention.

Example¹: *The classic process of obtaining plants or animals is not an invention. Likewise, processes that only have stages that mimic events occurring in nature are not considered invention. In contrast, the methods based on genetic engineering, where the technical intervention is significant, are considered invention.*

NON-PATENTABLE INVENTIONS - ARTICLE 18 OF THE BRAZILIAN IP STATUTE

§I. WHATEVER IS CONTRARY TO MORALS, GOOD CUSTOMS AND PUBLIC HEALTH, ORDER AND SECURITY - ITEM I OF ARTICLE 18 OF THE BRAZILIAN IP STATUTE

1.47 The examiner is not obligated to assess the economic and social effects of granting patents in specific fields of technology and the corresponding restriction of patentable matter.

1.48 Inventions can be considered non-patentable when it is necessary to prevent the exploration in their territory, in order to protect public order or morality, including protecting human, animal or vegetable life or health, or to prevent serious damage to the environment, provided that this determination is not made only because exploration is banned by its legislation.

1.49 Any invention whose commercial exploration is contrary to morality or public order is specifically excluded from

patentability. This aims to refuse a patent for typical inventions inducing chaos or public disorder or which lead to criminal or other generally offensive behavior. Landmines are an obvious example of this, although this provision is called upon only in rare and/or extreme cases. A correct test to be run is to consider whether it is likely that the general public would consider the invention so disturbing that it is inconceivable to grant patent rights. If this is clearly the case, an objection must be raised. The mere possibility of abuse of an invention is not sufficient to refuse patent protection if the invention can be explored in a way that does not infringe or would not infringe morality and public order.

1.50 Special attention should be paid to applications in which the invention has both an offensive and non-offensive use.

Example¹: *In a safe-opening process, the use by a thief, is considered offensive but not when a locksmith uses it in an emergency. In the latter case, there should be no objection.*

Example²: *Likewise, if a claim defines a copying machine resulting in enhanced accuracy of reproduction, and this type of machine can comprise additional characteristics – not claimed but apparent to person skilled in the art – having the sole purpose that it would also permit reproduction of safety strips on banknotes similar to those on genuine banknotes, the claimed apparatus would be the kind to fabricate falsified banknotes, considered to be contrary to public order. There is no reason, however, to consider that the copying machine, as claimed, is excluded from patentability, since its enhanced properties can be used for other acceptable purposes. Nevertheless, if the application contains an explicit reference to use contrary to morality or public order, an objection should be raised to remove this reference.*

1.51 In the case of biotechnology, considering that this is an invention-generating technological field that addresses matters that may raise questions on morality and public order, the current doctrine enables the BRTPO to refuse to patent these inventions pursuant to item I of article 18 of the Brazilian IP Statute. Non-exhaustive examples are as follows:

- i. processes of cloning the human being;
- ii. processes of modifying the human genome that causes the change in genetic identity of human germ cells; and
- iii. processes involving animals that cause their suffering without any substantial medical benefit for the human being or animal as a result from such processes.

§II. SUBSTANCES, MATTER, MIXTURES, ELEMENTS OR PRODUCTS OF ANY KIND, AS WELL AS THE MODIFICATION OF THEIR PHYSICAL- CHEMICAL PROPERTIES AND THE RESPECTIVE PROCESSES OF OBTAINING OR MODIFYING THEM, WHEN THEY RESULT FROM THE TRANSFORMATION OF THE ATOMIC NUCLEUS - ITEM I OF ARTICLE 18 OF THE BRAZILIAN IP STATUTE

1.52 Nuclear fission or fusion methods proper and their products are not patentable pursuant to item II do Art. 18 of the Brazilian IP Statute. However, the processes or methods involving radioactive materials but which do not consist of transforming the atom nucleus, may be patentable. For example, a method to separate deuterium and tritium from a hydrogen mass (which already contains these isotopes) would be patentable. The fact that a method is applied to nuclear engineering, for example in a reactor or accelerator of particles, does not necessarily mean that it disagrees with the aforementioned item. A magnetic confinement method, for example, can be used to produce both Bose-Einstein condensates (not vetoed by the item) and substances of nuclear fusion (vetoed by the item). In the latter case, the examiner must identify the technical problem to be solved and check whether the application in question directly or indirectly requests the fusion or fission (vetoed by the item) process proper, or the objective

is the confinement-related technologies, power generation by using particles, or heat emissions in the nuclear reaction, or containment materials (not vetoed by the item).

1.53 Moreover, it should be mentioned that the item in question does not veto the patenting of devices, machinery, equipment or arrangements associated with nuclear technology. The aforementioned magnetic confinement can be implemented from an experimental arrangement that, if consisting of industrial application, novelty and inventive step for state of the art, it may receive the required patent. Likewise, other examples of these technologies are particle-detecting equipment and electromagnetic radiation, gas pumping, vacuum pumps and chambers, sensors, control systems, and so on.

1.54 Other examples of vetoed matters pursuant to item II of article 18 of the Brazilian IP Statute are as follows.

Example¹: *Enrichment method of radioactive isotopes where the nuclei are excited by high-energy electrons and photons (in XR form), or even by a laser as described in document US6137073;*

Example²: *Method of producing radioactive isotopes using particle accelerators, as described in document US20110194662;*

Example³: *Nuclear fusion method to produce light elements to be used as fuel in a second nuclear reactor, as described in document WO2009142530.*

1.55 Examples of matters that are not vetoed in accordance with item II of article 18 of the Brazilian IP Statute are mentioned as follows.

Example¹: *Method of internal control of a reactor using an electric device, as stated in document WO2012078939;*

Example²: *Automated depressurization system in a nuclear reactor, as in document US201201655597;*

Example³: *Shutdown system of a nuclear reactor, as described in document EP2463864;*

Example⁴: *Compact pressurized water nuclear reactor (PWR), as described in document US20120076254;*

Example⁵: *Reactor to produce controlled nuclear fusion, as described in document WO2012003524.*

§III. LIVING BEINGS, IN WHOLE OR IN PART, EXCEPT TRANSGENIC MICRO-ORGANISMS MEETING THE THREE PATENTABILITY REQUIREMENTS - NOVELTY, INVENTIVE ACTIVITY AND INDUSTRIAL APPLICATION – PROVIDED FOR IN ARTICLE 8 AND WHICH ARE NOT MERE DISCOVERIES - ITEM III OF ARTICLE 18 OF THE BRAZILIAN IP STATUTE

1.56 In relation to transgenic microorganisms, the sole ¶ of article 18 (III) of the Brazilian IP Statute defines that “For the purpose of this Statute, transgenic microorganisms are organisms, except all or part of plants or animals, which express through direct human intervention in their genetic composition a characteristic normally unachievable by the species in natural conditions.”

1.57 According to this definition, the term transgenic microorganism includes microorganisms obtained from any

technique resulting in the alteration of the genetic composition by direct human interference, and which cannot be achieved by the species in natural conditions.

1.58 The general term “microorganism” is used for bacteria, archaea, fungi, unicell algae that are not classified in the Plant Kingdom and protozoa. Thus, within all or part of the living beings, natural or transgenic, the Brazilian IP Statute permits patenting only of transgenic microorganisms.

CHAPTER II. INDUSTRIAL APPLICATION

2.01 Article 15 of the Brazilian IP Statute determines that the invention is considered susceptible of industrial application when it can be used or produced in any kind of industry. The concept of industrial application should be analyzed in the broadest sense and shall also apply to agricultural and extractive industries and to all manufactured goods, since endowed with repeatability.

2.02 The term industry should be understood to include any technical activity that is not individualized, that is, personalized and/or specific for one individual only, with no repeatability characteristic.

Example¹: *A basketball throwing method.*

2.03 Considering the fact that an industry does not exist in the sense of making or using something that does not have a known purpose, it is necessary for the claimed invention to have a utility and that the specification identifies any practical way of exploring it. Thus, purely abstract concepts or speculative indications do not satisfy the requirement of industrial application.

2.04 The concept of industrial application does not necessarily imply the use of a machine or manufacture of an article.

Example¹: *Demisting process.*

Example²: *Conversion of one form of energy to another.*

2.05 The invention with no industrial application is one that can be operated in a way clearly contrary to the established Statutes of physics.

Example: *Perpetual motion machine.*

2.06 Testing methods should generally be considered as inventions for industrial application and, therefore, patentable, if the test is applicable for improving or controlling a product, apparatus or process that, in itself, is considered feasible for industrial application, such as, for example, testing industrial products or some other phenomenon (e.g. to determine air or water pollution), is considered likely for industrial application.

CHAPTER III. STATE OF THE ART

DEFINITION AND GENERAL CONCEPTS

3.01 According to the ¶1 of article 11 of the Brazilian IP Statute, state of the art consists of anything considered

accessible to the public before the date of the deposit of the patent application, by written or oral description, use or any other means, in Brazil or abroad, except for the provision in article 12 – grace period; article 16 – right of priority, and article 17 – internal priority of the Brazilian IP Statute.

3.02 There are no geographic or linguistic restraints, or means by which relevant information was made accessible to the public, as well as none time limit stipulated for the documents or other sources of information.

RELEVANT DATE FOR SEARCHING PRIOR ART

3.03 The date to be used to search prior art shall be considered the relevant date; in other words, the date of deposit or of priority, if any. It should also be recalled that different claims or different alternatives requested in a claim could have different relevant dates. The patentability requirements shall be analyzed for each claim, or part of a claim when this has several alternatives. The state of the art relating to a claim or part of a claim may include material that may not be mentioned against another claim or part of a claim, because the latter has an earlier relevant date. Evidently, if all documents of the state of the art were available to the public before the date of the oldest document of prior art, the examiner shall not be concerned with associating priority dates for each claimed matter.

3.04 A written description, such as a document, should be considered available to the public if, on the relevant date, it was possible for the public to be aware of the document's content, and if there were no issues of confidentiality restricting the use or dissemination of such contents.

Example: *German utility models are readily available to the public on their deposit date, which precedes the official publication date.*

3.05 The search report should not mention documents in which there are doubts relating to their availability to the public and the precise date of publication of any document.

SUFFICIENCY OF DISCLOSURE

3.06 A matter can only be considered accessible to the public and thus comprising state of the art, pursuant to the ¶1 of article 11 of the Brazilian IP Statute, if the information provided is suitable for someone skilled in the art to put such a matter into practice, considering general knowledge in the specific field of the material available at that time.

3.07 The prior art cannot be a mere abstraction but its implementation should be feasible to perform.

Example: *A patent application claims a shipwreck salvage method, consisting of inserting floats inside the ship through a pipe launched by a salvage vessel. By this method, the insertion of the floats proceeds until the thrust is sufficient to raise the ship from the seabed and bring it to the surface. A 1949 comic book of Donald Duck "The Sunken Yacht, by Carl Barks", which describes a method for recovering shipwrecks using table tennis balls could not be used as state of the art for this application, since the comic book does not give sufficient information to consolidate the method described therein.*

DOCUMENTS IN UNOFFICIAL LANGUAGE

3.08 It is administrative practice of BRPTO to use foreign documents in searches during the examination of the patent. Therefore, there is no obstacle against using documents presented in a language other than Portuguese.

3.09 If the applicant or third parties submit documents in a foreign language of which the examiner has no knowledge, he may request a simple translation to Portuguese, or this same document may be presented in another language known by the examiner, and a statement from the interested party that such translation is true to the original document, based on article 22, §1, of Statute no. 9.784 – a Statute that establishes basic rules about the administrative process in the framework of the direct and indirect Federal Administration, especially in order to protect the rights of the administered and best achieve the purposes of the Administration.

3.10 On the other hand, in the case where the examiner presents a document in a foreign language that the applicant has no domain, the latter may request BRPTO for a simple translation of the parts of the document used in the opinion. In this case, the examiner may resort to machine translation.

PRIOR ART DOCUMENTS UNPUBLISHED ON THE RELEVANT DATE OF THE APPLICATION UNDER EXAMINATION (ARTICLE 11 §2 OF THE BRAZILIAN IP STATUTE)

3.11 The state of the art also consists of the full contents of applications deposited in Brazil, whose date of filing or priority is earlier than the date of the filing application in question, but which has been published, even if after this date. Such documents are only used for the purpose of assessing a novelty. “Full contents” is understood to be complete disclosure, that is, the specification, drawings, claims and abstract, including:

- i. any matter explicitly revealed;
- ii. any matter for which a valid reference to other documents is made, such as, if a document is in an application as originally filled, the contents of this document are considered part of the state of the art; and
- iii. state of the art as explicitly described.

MEANS OF DISCLOSURE

3.12 The means of disclosure of state of the art include published documents, disclosure by use and disclosure by other means.

Example: *Oral disclosure.*

3.13 It is important that such disclosures include the following elements: certainty regarding the existence and date; sufficiency of disclosure so that person skilled in the art is able to duly understand the content of the exposed matter; and publicity, that is, available or likely to be known by third parties (public).

3.14 The expression “accessible to the public” pursuant to the ¶1 of article 11 of the Brazilian IP Statute represents situations where anyone can access the information. It is not necessary for this information to actually become known, simply this possibility.

3.15 It should be noted that technical information in secret conditions is not part of state of the art. The condition of a secret includes situations where the obligation to keep the secret arises from regulations and agreements of confidentiality.

3.16 However, if someone having the obligation to keep a secret breaks this rule, agreement or implicit understanding, describing the information and making the technologies available to the public, these technologies should be part of state of the art.

§I. PUBLISHED DOCUMENTS

3.17 Published documents are means of dissemination that should indicate or present any other evidence that proves the date of publication.

3.18 The documents as defined above may be printed or typed, such as patent documents, scientific and technical journals and books, annals of events, such as symposia, seminars and workshops, doctoral theses, masters dissertations, monographs, technical standards, specialized documents, textbooks, proceedings or technical reports published officially, journals, product catalogs, and advertising brochures. They may also include audio or video material obtained from an electric, optic, magnetic or photographic medium, such as microfiches, films, negatives, videotapes, tapes, DVDs and CD-ROMs. They may also be documents on the Internet or in the form of other online databases.

3.19 In the case of doctoral thesis, master's dissertations and monographs, the relevant date to be considered for publication will be the defense date, unless the cases where such defense is performed in conditions of secrecy, where the relevant date will be the publication date of the document, if applicable.

3.20 The framework of a document as a description should not be affected by the place or language of publication, procurement method or its age. The print-run, or if the applicant is aware of it, is also not relevant.

3.21 Regarding the documents published with the words "Internal Material" or "Restricted Publication" or other similar words, if in fact they were distributed in a restricted environment and had to be kept confidential, they are not regarded as published documents in the Brazilian IP Statute context.

3.22 The date of a publication is considered the date of disclosure. When only the specific month or year is indicated as the publication date, the last day of the month or year must be considered as the disclosure date. Normally, in original documents the dates are located on the cover sheet, that is, on the front page of the document. In some cases, the date is only mentioned at the end of the publication. However, when there is no description that enables identifying the document's date, the BRPTO Library may be demanded to search by contacting the publishers.

3.23 The certainty regarding the date and sufficiency of disclosure of the document of prior art can be proven, for example, by means of a duly dated invoice and which indisputably specifies the product. Catalogs and factory drawings may be used with the invoices in order to permit the characterization of the document regarding its sufficiency of disclosure, so that the complete proof – invoice and catalog/drawing – leaves no doubt that the object is in fact that intended to be contested.

§II. ORAL DISCLOSURE

3.24 Oral disclosure includes conversations, reports, symposium lectures, radiobroadcasting, television broadcasting and cinematography that may convey known technical information to the public. For information from conversations, reports or symposium lectures, the date of action must be considered the date of the disclosure. For information of radiobroadcasting, television broadcasting or cinematography, which can be received by the public, the transmission date or show must be considered the disclosure date.

3.25 It should be mentioned that any oral disclosure should be accompanied by evidence of its origin, its content by registration, and date of disclosure, such as, for example, a transcription of a lecture.

§III. DISCLOSURE BY USE

3.26 Disclosure by use means the use of the technical solution is placed in a condition to be assessed by the public.

3.27 Means of disclosure by use include producing, using, selling, importing, exchanging, presenting, demonstrating or exhibiting, which may make technical information available to the public. To the extent that by the above means the technical information is made available for public knowledge, the disclosure by use can be established, and it is not relevant whether if the public in fact know it. However, if, when exhibiting or demonstrating a product, no explanation of its technical content is provided so that the structure and function or composition of the product is unknown to person skilled in the art, the exhibition or demonstration is not disclosure by use.

3.28 When disclosure by use refers to a product, it can be established even if the product or device used requires reverse engineering in order to know its structure and function. Moreover, disclosure by use also includes the disclosure on an exhibition stand or showcase of informative material or directly visible materials, for the public's understanding, such as posters, drawings, photographs, copies and samples.

3.29 The date when the product or process is available to the public should be considered to be the date of disclosure by use.

3.30 In the case of a document, for example, such as a newspaper article, which reproduces an oral disclosure, such as a public conference, or information given of previous use, such as a sample in a public exhibition, oral disclosure or prior use having been made available to the public before the application deposit date, even if the document itself has been published after the said date of deposit, the examiner should assume that the document faithfully represents the public conference, display or exhibition and, therefore, consider this document as part of state of the art.

MATERIAL FOUND ON THE INTERNET USED AS PRIOR ART

3.31 Contents from the Internet are only acceptable as prior art in case of the publication date is proven.

3.32 Restricted access to a limited circle of people, for example, by password, or request to pay for access – like buying a book or subscribing to a newspaper – does not prevent a web page from being part of state of the art. The web page only needs, in principle, to be available without any degree of confidentiality. Web pages in which information is coded so that it cannot be read in general – excluding cases where a decoding tool is widely accessible, with or without paying a charge – is a case where information is considered not accessible to the public. If before the deposit date or prior art of the patent application, a document stored in the Internet and accessible through a virtual address (1) could be found with the help of an Internet public search tool through one or more key words, all relating to the essence of the document's matter, and (2) could remain accessible at the address for a long enough period of time for anyone, that is, anyone with no obligation to keep the document a secret, has direct access and without ambiguities in the document, then the document will be available to the public pursuant to the ¶1 of article 11 of the Brazilian IP Statute.

3.33 In relation to the matter disclosed in e-mails, it cannot be considered a document accessible to the public, since they are understood to be confidential documents.

3.34 The term “internet” refers to all media offering technical information through electric telecommunication media, including the Internet, business databases and mailing lists.

3.35 Disclosures on the Internet are included in state of the art pursuant to the ¶1 of article 11 of the Brazilian IP Statute. Information disclosed on the Internet or in online databases is considered available to the public from the date when the information has been publicly disclosed. Web pages often contain information of major technical relevance. Some information can even be available only on the Internet from such web pages.

Example: *Online manuals and tutorials for software or other products with a short lifespan.*

3.36 In order to determine the state of the art of a patent application, it is very often important to mention publications that may be obtained from web pages.

§I. ASSIGNMENT OF PUBLICATION DATE

3.36 Electronic technical information with no projected publication date cannot be cited as state of the art.

3.37 There are two aspects when assigning a publication date. It should be evaluated separately if a certain date is correctly indicated, and if the content in question was actually available to the public from that date.

3.38 The nature of the Internet may make it harder to assign the actual date when the information has been made accessible to the public.

Example: *Not all web pages mention when they were published. Moreover, web pages are easily updated, but the majority does not provide records of previously presented material, or shows those that allow the public to accurately establish what was published and when.*

3.39 When an Internet document is mentioned against an application or patent, the same considerations should be made as for any other reference, including standard hardcopy publications. In many cases, Internet documents provide an explicit publication date. These dates in principle are accepted and the burden of proof otherwise will be for the applicant and circumstantial evidence may be required to establish or confirm the publication date.

3.40 While the dates of disclosure contents on the Internet can be considered in principle as valid, there are, of course, different degrees of reliability. The more reliable the date of the disclosure source, the harder for the applicant to contest it.

3.41 When an Internet disclosure is relevant for the examination, but fails to give any explicit indication of the publication date in the disclosure text, or if the applicant questions whether a certain date is not reliable, the examiner can attempt to obtain further proof to assign or confirm the publication date. Specifically the examiner may consider using the following information:

- i. Information related to a web page available through an Internet archiving service, such as Internet Archive, accessible through the so-called “Wayback Machine” - www.archive.org. The fact that the Internet Archive is incomplete does not reduce the credibility of the filed data. Legal exceptions relating to the accuracy of the supplied information, routinely used in web pages, should not be considered as negatively reflecting their accuracy;

- ii. Date record relating to past modifications applied to an archive or web page, such as available for Wiki pages, namely Wikipedia, and in version control systems, as used for developing distributed software;
- iii. Date record created by a computer as available from archive directories or other repositories, or automatically added to the content, such as discussion groups, indexation dates attributed to the web page by search tools, such as, for example, from the Google cache. These dates will be later than the publication date of the document, since the search tools take some time to index a new web page;
- iv. Information about replication of disclosures on different web pages – mirror pages – or in different versions.

3.42 It is also possible to make inquiries with the owner or author of the web page when attempting to assign the publication date a sufficient degree of certainty.

3.43 The following §§ deal with the reliability of the different types of Internet disclosure.

§II. TECHNICAL JOURNALS

3.44 Online technical journals from scientific publishers are particularly valuable in determining state of the art. These publications are as highly reliable as the traditional hardcopy journals.

3.45 It is noticeable that the publication in the Internet of a specific subject in a journal may be prior to the publication date of the corresponding hardcopy version. In this case, the earlier publication date of the document is to be considered.

3.46 If the publication date of an online journal is vague, only indicating the month and year, and the most pessimistic possibility - the last day of the month – is too late, the examiner may request the exact date of publication. This request can be made directly by contact form offered online by the publisher on the Internet, or through the BRPTO library.

3.47 The information published in the following web pages are considered reliable:

- i. websites of publishers that have issued well-established publications, such as websites with the electronic data of journals, magazines, that offer electronic publications of academic journals;
- ii. websites of academic institutions, such as homepages of academic institutions and universities;
- iii. websites of international organizations, such as standardization agencies that publish information about measurement standards; and
- iv. websites of public organizations, such as ministries and agencies that publish details of research work, news of scientific discoveries, especially research institutes.

§III. OTHER PUBLICATIONS

3.48 The Internet is also used to exchange and publish information in other formats, for example, chat rooms, blogs, chat room e-mail files or Wikipedia pages. The documents obtained from such sources also include state of the art, since the date of publication can be correctly established and the content is available to the public.

3.49 Date-scheduling by the provider of a certain service – generally seen in, for example, blogs, chat rooms or the background of a version available from Wikipedia pages – can be considered as reliable publication dates.

§IV. TECHNICAL DETAILS AND GENERAL COMMENTS

3.50 Internet pages are sometimes divided into frames, whose content is created from different sources. Each frame may have its own publication date, which can be checked. Should the examiner use such a document, he/she must certify they are using the correct publication date, that is, that the publication date mentioned refers to the intended content.

3.51 Some web addresses - URLs are temporary, for example when they are designed to work only for a single session – while the user is logged into the web page. Long URLs with apparently random numbers and letters are indicative of these. The presence of such a URL does not prevent disclosure of being used as state of the art, although the URL does not work for other people - for example: the applicant when receiving the search report. For temporary URLs, the examiner shall indicate how he reached this specific URL of its web page, that is, which links were followed or what research terms were used.

3.54 When printing an Internet page, care should be taken to for the complete URL to be clearly legible. The same applies to the relevant publication date on a web page.

3.55 It should be borne in mind that the publication dates can be presented in different formats, especially in the Brazilian/European format dd/mm/yyyy, in the American format mm/dd/yyyy, or in the ISO format yyyy/mm/dd. Unless the format is explicitly indicated, it will be impossible to distinguish between the Brazilian and American format for day 1-12 of each month.

3.56 The examiner should always indicate the date when the web page was accessed. When mentioning the Internet disclosure he must present the data of the state of the art document, such as, when and where the publication date was obtained, and any other relevant information.

Example: *Where two or more related documents are mentioned, how they are related, and/or indicating that a certain link in the first leads to the second document .*

Example according to the ABNT electronic format:

KRUG, C.A.; ANTUNES FILHO, H. Melhoria do cafeeiro: III - Comparação entre progênies e híbridos da var. bourbon. *Bragantia*, Campinas, v. 10, no. 11, 1950. Disponível em <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0006-87051950001100004&lng=pt&nrm=iso>. acessos em 25 jul.2012. <http://dx.doi.org/10.1590/S0006-87051950001100004>.

CROSS-REFERENCES BETWEEN THE STATE OF THE ART DOCUMENTS

3.57 If a “primary” document refers explicitly to another “secondary” document as providing more detailed information about certain characteristics, the learning from the latter should be considered as incorporated into primary document, if the document were available to the public on the publication date of the primary document. The relevant date for the purpose of examining a novelty, however, is always the date of the primary document.

ERRORS IN STATE OF THE ART DOCUMENTS

3.58 Errors can exist in state of the art documents, such as, for example, a document that describes a chemical

compound with pentavalent carbon. Using general knowledge, someone skilled in the art can:

- i. clearly see that the disclosure of a relevant document of state of the art contains errors, and
- ii. identify what would be the only possible correction.

3.59 Thus, errors in disclosure do not affect its relevance as state of the art, and the document can be considered for assessing its relevance for patentability.

GRACE PERIOD - ARTICLE 12 OF THE BRAZILIAN IP STATUTE

3.60 The grace period sets an exception to state of the art. Disclosures by the inventor proper of the application of an invention patent, by the BRPTO without the inventor's consent or by third parties based on information obtained directly or indirectly from the inventor will not be considered state of the art, provided they occurred 12 (twelve) months prior to the deposit date of the application or of its claimed prior art, pursuant to article 12 of the Brazilian IP Statute.

3.61 It is worth mentioning that the disclosures acceptable for the grace period are non-patentable documents.

Example: *Publication of a scientific article and oral communications provided there is a registration of them, such as a transcription.*

3.62 So a patent application by the inventor proper, prior to the application under analysis, cannot be considered a disclosure that fits the terms of the grace period.

3.63 Therefore, once a document of the inventor proper fits the provision in article 12 of the Brazilian IP Statute, the examiner should not use the document to make objections regarding the novelty of the application, but should mention it in the search report and opinion, justifying in this last the non-use for objections, because it is included in the grace period.

CHAPTER IV. NOVELTY

4.01 According to article 8 of the Brazilian IP Statute, any invention for which a patent right can be granted should have novelty, inventive step and industrial application. Accordingly, novelty is one of the patentability requirements to be satisfied so that an invention receives a patent right.

4.02 According to the provision in article 11 of the Brazilian IP Statute, the invention is considered new when not understood in the state of the art.

4.03 The requirement of novelty should be noted for each claim in the patent application. If an independent claim shows novelty, it is not necessary to examine the novelty of its dependent claims, since they will all have novelty.

4.04 On the other hand, if the independent claim fails to show novelty, its dependent claims must be examined, since they may contain specific elements to make it a new matter.

4.05 The novelty required for a claim should be investigated with regard to the overall claim, and not only on its characterizing part, nor on the individual analysis of the elements comprising it, which may separately be covered

by state of the art. Thus, if the preamble defines the A and B characteristics, and the characterizing part defines the C and D characteristics, no matter if C and/or D are known individually, but rather if they are known in association with A and B – not only with A nor only with B, but with both.

4.06 The matter under examination will not be new when all characteristics of a certain claim (elements or a product or stages in a process), including the characteristics addressed in the preamble, are disclosed in a single prior art. Such characteristics can be found in the prior art when they are clearly presented and/or when there is no doubt that the information is inherent to what has been literally disclosed.

4.07 The lack of novelty in a document found in state of the art cannot be based on possibilities, hypotheses or speculations from the matter disclosed in the prior art. The relationship between the compared documents must have a strict identity, which means that a single document should describe each element of the claim analyzed, either explicitly or inherently, otherwise the question shifts to analysis of an inventive step.

4.08 To analyze the novelty requirement, it is not possible to combine two different documents of state of the art. When such a combination is necessary, only the inventive step should be discussed. However, more than one document of state of the art can be mentioned for arguments against the novelty of the claimed matter, provided it is not necessary for these prior arts to be combined to support such allegations, as in the following cases:

- i. different documents may be used to discuss the novelty of matters in different claims;
- ii. for different alternatives in the same claim, Markush claims, different prior arts can be used regarding the novelty of the matter of the same claim, when each prior art refers to different alternatives within the possibilities offered by the claim. It is worth emphasizing that when analyzing claims with alternatives, a prior art that discloses one of the alternatives is sufficient to remove the novelty from the overall claim. However, reformulations of the claim are acceptable in order to exclude the matter found in the state of the art;
- iii. a second document can be mentioned, such as a dictionary or similar reference document in the discussion about the novelty of the matter of a claim, in order to interpret the meaning of a specific term, such as, to confirm that cheese is a dairy product, or to demonstrate a synonym, emphasizing that only the first prior art mentioned is a deterrent to the novelty of the claimed matter;
- iv. when a state of the art document makes reference to a second published document, the latter will be considered included by reference to the first.

4.09 For the assessment of novelty, the examiner should take the following steps:

- i. identifying the elements contained in the claim;
- ii. determining whether a document under analysis belongs to state of the art - Chapter III of the Guidelines herein; determining whether all elements or steps in the claim have been explicitly or inherently combined in the document, for person skilled in the art, on the document's publication date, and in order to anticipate the claim.

4.10 It is also important delimit the understanding of what is a deductible technical information directly and unambiguously from the prior art document. Thus, when considering novelty, it is not correct to interpret the learnings of a state of the art document as involving well known equivalents, which are not described explicitly in said document; this is a question related to the obvious, that is, the inventive step.

SPECIFIC TERM AND GENERAL TERM

4.11 When the matter is claimed on a broad and general basis, and there is a document in the state of the art where the matter is disclosed specifically within the parameters claimed in the application under examination, the absence of novelty should be indicated. For example, a product “made of copper” described in a prior art document affects the novelty of an invention for the same product “made of metal”. However, disclosure of the copper product does not affect the novelty of an invention for the same product made in another specific metal.

4.12 On the other hand, a disclosure in general terms does not affect the novelty of an invention defined in specific terms.

Example¹: *A product “made of metal” described in a prior art document does not affect the novelty of an invention for the same product “made of copper”.*

Example²: *A claim of food composition consisting of a dairy product is not new given a priori art in which a food is presented with the same composition, in which “dairy product” is substituted by “cheese”. In this case, there is no doubt that the cheese is a dairy product, and therefore the prior art implicitly discloses an identical composition to the claimed composition containing a dairy product (cheese).*

4.13 It should be mentioned that this understanding does not apply in the inverse situation where the prior art generally mentions dairy product and the claim refers to cheese, since not every dairy product is cheese. Therefore, general documents do not anticipate specific matter.

NUMERICAL VALUE AND NUMERICAL RANGE

4.15 If the claimed invention contains a technical characteristic defined by numerical values or a continuous numerical range, such as, dimensions of a component, temperature, pressure or content of components in a composition, and every other technical characteristic is identical to those in a prior art document, then the novelty should be determined according to the following rules:

- i. When the numerical values or numerical ranges described in the prior art document fall entirely into the claimed range of the technical characteristic, the prior art document affects the novelty of the application.

Example¹: *The application claims a copper-based alloy consisting of 10%-35% weight of zinc, 2%-8% weight of aluminum, and the rest is copper. If the prior art document describes a copper-based alloy consisting of 20% weight of zinc and 5% weight of aluminum, this affects the novelty of the aforementioned claim.*

Example²: *The application claims a heat-treatment furnace, where its linear arch is 100-400 mm in thickness. If the prior art document describes a heat-treatment furnace in which the thickness of the linear arch is 180-250 mm, this document affects the novelty of said claim.*

- i. When the numerical range described in the prior art document and the numerical range of the technical characteristic partly overlap or show at least one extreme point in common, the prior art document affects the novelty of the invention.

Example¹: *The application claims a process to produce silicon nitride ceramics, where the calcination time is 1-10*

hours. If the prior art document describes a process for the production of silicon nitride ceramics where the calcination time is 4-10 hours, since both ranges overlap in the calcination time of 4-10 hours, the prior art document affects the novelty of said claim, but does not affect the novelty of said claim in the case of the calcination time of 1-4 hours.

Example²: The application claims a spray-coating process, where the spray gun power is 20-50 kW during coating. If the prior art document describes a spray coating process in which the spray gun power is 50-80 kW during coating, since the two ranges present an extreme point in common, 50 kW, the prior art document affects the novelty of said claim.

- i. The two end-points of the numerical range described in the prior art document affect the invention's novelty when the technical characteristic in question has discrete numerical values, including one of the said end points, but does not affect the invention's novelty when the technical characteristic in question is a numerical value at any point between both end points.

Example¹: The application claims a process for producing a titanium dioxide photocatalyst, where the drying temperature is 40°C, 58°C, 75°C or 100°C. If the prior art document describes a process for the titanium dioxide photocatalyst production where the drying temperature is 40°C-100°C, this disclosure affects the novelty of said claim in the case of a drying temperature of 40°C or 100°C, but does not affect the novelty of said claim in the case of the drying temperature of 58°C or 75°C, thereby the claim should be reformulated.

- i. When the numerical values or numerical range of the technical characteristic in question falls within the range described in the prior art document and has no end point in common with the latter, the prior art document does not affect the novelty of the claimed invention.

Example¹: The application claims a piston ring for an internal combustion engine, where the diameter of the piston ring is 95 mm. If the prior art document describes a piston ring 70-105 mm in diameter used in an internal combustion engine, this does not exclude the novelty from said claim, as long as the 95 mm ring has not been explicitly mentioned and consolidated in the prior art.

Example²: The application claims an ethylene-propylene copolymer, where the polymerization grade is 100-200. If the prior art document describes an ethylene-propylene copolymer in which the polymerization grade is 50-400, this does not exclude the novelty from said claim, as long as the polymerization grade of 100-200 has not been explicitly mentioned and consolidated in the prior art.

4.16 For further details regarding selection patents, see paragraph 4.24 herein.

CLAIMS OF A PRODUCT DEFINED BY CHARACTERISTICS OF PERFORMANCE, PARAMETERS, USE OR MANUFACTURING PROCESS

4.17 The following rules should be followed for the examination of the novelty of claims of a product including characteristics of performance, parameters, use, or manufacturing process.

4.18 Claims of a product defined by characteristics of performance or parameters: For this type of claim the examiner should consider if the characteristic of performance or parameters in the claim implies the fact of the claimed product having a certain structure and/or particular composition. If the performance or parameters imply the fact that the claimed product has a different structure and/or composition from the product described in

the prior art document, the claim presents novelty. On the other hand, if person skilled in the art, based on the performance or parameters, cannot distinguish the claimed product from that described in the prior art document, it can be presumed that the claimed product is identical to that in the prior art document and, thus, the claim does not present novelty.

Example: *An application claims a compound A in a crystalline state defined by a variety of parameters, including X-ray diffraction data, and the prior art document also describes a compound A in a crystalline state. If the crystalline states of both cannot be distinguished from each other after the description of the prior art document based on these parameters, it is presumable that the claimed product is identical to the product of the prior art document and, therefore, the claim does not present novelty.*

4.19 Claims of a product characterized by use:

For this kind of claim, the examiner must consider whether the characteristic of use implies the fact that the claimed product has a certain structure and/or particular composition. If the use is fully determined by the product's inherent property and does not imply any alternation to the product's structure and/or composition, the product claim defined by its characteristic of use does not present novelty compared to the product of the prior art document.

Example: *A claim for a compound X for use as an antiviral would not be considered new in relation to the same compound X used as a dye described in a prior art document. Although the use of compound X has been changed, the chemical formula that determines its properties has not been altered. Therefore, the invention of the antiviral compound X does not show novelty.*

4.20 However, if the use indicates that the structure and/or composition of the product has been altered, then the use as a characteristic defining the product's structure and/or composition, as well as the product, has novelty.

Example: *If a claim refers to a mold for liquid steel, this implies certain limitations for the mold. Thus, a plastic ice tray with a much lower melting point than that of steel does not affect the novelty of the claim.*

4.21 For new products characterized by use, they should have their own characteristics in order to clarify the claim.

4.22 Claims of a product characterized by the manufacturing process:

For this type of claim, the examiner should consider whether the manufacturing process characteristic results in a particular structure and/or particular composition of the product. If person skilled in the art can conclude that the process will necessarily result in a product with a different structure and/or composition from that of the product in the prior art document, the claim has novelty. On the other hand, if the claimed product, when compared to the product in the prior art document, has the same structure and composition despite the different manufacturing process, the product claim does not have novelty.

Example: *The application claims a glass obtained by the X process, and a prior art document describes a glass obtained by process Y. If the glasses obtained by both processes have the same structure, format and constituent material, the product's claim does not have novelty. On the other hand, if the X process consists of a curing stage at a particular temperature not described in the prior art document, which considerably increases the resistance against breaking the glass, when compared to the glass in the prior art document, then this indicates that the claimed glass has a different*

microstructure due to the different manufacturing process, and has an internal structure different from that of the glass in the prior art document. Accordingly, the claim presents novelty.

CLAIMS OF SECOND NON-MEDICAL USE

4.23 A claim for using a compound known for a particular purpose – non-medical use, which is based on a technical effect, should be interpreted as including the technical effect as a functional technical characteristic. Thus, this claim has novelty, provided that such a technical characteristic has not been previously available to the public.

SELECTION PATENTS

4.24 An invention by selection consists of choosing individual elements, subgroups or ranges within a general description of state of the art, whether within options for substituents in a compound, components present in compositions or ranges of process parameters, and which have particular and unexpected properties of their own, in relation to the closest state of the art. It is possible to find selection patents in applications of processes involving particular conditions not specifically disclosed previously in the state of the art, and/or in product applications selected from products defined comprehensively, typically in Markush product formulas, and also, for example, in derived compounds and compositions.

4.25 The selection patent should adopt the following criteria:

- i. The selected component may not have been specifically disclosed to meet the novelty criterion;
- ii. The selected component should present some clearly demonstrated and unexpected technical effect, to meet the inventive step criterion (see the topic “Invention by Selection” in the chapter on Inventive step).

4.26 It is understood that specifically disclosed is that matter contained in the body of the application, whether in the specification, drawings, examples of preparation/use, or in the drawings, or in the claims, clearly and concretely, without requiring the examiner’s deduction.

4.27 Thus, the novelty for such selection may be attributed if the description in a prior document is only general, without explicitly mentioning the specific item that is being selected, that is, textually and embodied as examples, tests and results. Therefore, a general prior description itself does not remove the novelty from a disclosed specific matter.

4.28 If a product was disclosed in a document of the state of the art, for example, a compound, through its name, or by its structural formula, within the said preferential and embodied compounds in the preparation/use examples, this cannot be the subject matter of a selection patent, since the compound is considered as specifically disclosed and fails to meet the novelty requirement.

4.29 In the case of process selection applications where a subrange is selected from a wider range comprised in the document of the state of the art, in order to meet the novelty requirement it is necessary for the selected subrange has not been specifically disclosed and embodied in the state of the art, and do not include parts of the range specifically disclosed in a prior document.

Example¹: *A patent application addresses a process for obtaining a product, with temperature control between 125°C and 130°C. The state of the art discloses the same process for obtaining the product, using temperatures of 120°C to 180°C, with tests presented using temperatures of 140°C and 150°C. In the latter case, the claimed process is new,*

bearing in mind that it addresses a specific temperature selection in a comparatively wide interval different from that explicitly disclosed and consolidated in the state of the art.

Example²: A patent application addresses a process for obtaining a product with temperature control between 125°C and 140°C. The state of the art discloses the same process to obtain the product, using temperatures of 120°C to 160°C, with tests presented using temperatures of 140°C and 150°C. In the latter case, the claimed process includes a temperature that was explicitly disclosed and consolidated in the state of the art (140°C), and therefore the selection of the claimed temperature range is not considered new.

4.30 Person skilled in the art must consider that the numerical values relating to measurements are subject to errors that limit their accuracy. For this reason, the general convention in scientific and technical literature is applicable, in which the last decimal place of a numerical value indicates its degree of accuracy. In cases where there is no other margin of error, the maximum margin should be determined by rounding off the last decimal place.

Example: In a measurement of 3.5 cm, the margin of error is 3.45 to 3.54 cm.

CHAPTER V. INVENTIVE STEP

CONCEPT

5.01 The invention has an inventive step, provided in article 13 of the Brazilian IP Statute if, taking into account the state of the art, it does not occur in an evident or obvious manner for person skilled in the art. Novelty and inventive step are different criteria and the question – “does an inventive step exist?” – only arises if the invention is new.

5.02 The term “evident or obvious” means something that does not go beyond the normal development of technology, but only does so clearly or logically from state of the art, that is, something that does not involve exercising any skill or ability beyond what is expected from person skilled in the art.

5.03 If person skilled in the art can arrive at the invention solely by logical analysis, inference or without undue experimentation based on state of the art, following the instructions presented in the Guidelines for Patent Application Examination - Block I, the invention is obvious and, therefore, does not have any unexpected technical solution. If this is the case, the application is not patentable due to lack of an inventive step.

STATE OF THE ART

5.04 In order to analyze an inventive step, the “state of the art” as provided in the first paragraph of article 11 of the Brazilian IP Statute should be understood as relating to any relevant information for a certain technological area; that is, it consists of all information made accessible to the public before the deposit or priority – if any, of the application under examination, which is the relevant date for the application and does not include documents pursuant to the ¶2 of article 11 of the Brazilian IP Statute.

PERSON SKILLED IN THE ART

5.05 Person skilled in the art, for the purpose of an inventive step, presents the same concept referring to the sufficiency of disclosure.

ASSESSMENT OF INVENTIVE STEP

§I. OVERVIEW

5.06 To assess the inventive step, the examiner must consider not only the technical solution itself, but also the technical field to which the invention belongs, the solved technical problem and the technical effects produced by the invention.

5.07 The claimed invention should be considered as a whole, taking into account the elements in the preamble and characterizing part. When determining the differences between the claims and state of the art, the question is not whether the differences would be obvious individually, but if the claimed invention would be obvious as a whole. Accordingly, as a general rule, in the case of claims combining various characteristics, it is not correct to consider the claimed matter as obvious, under the argument that the various said technical characteristics, each regarded separately, are known or obvious in relation to state of the art. However, when the claim is merely an “aggregation” or “juxtaposition” of known characteristics, that is, a combination resulting in an effect that is the mere sum of the individual effects of the characteristics, this claim does not have an inventive step.

5.08 Generally, if an independent claim involves an inventive step, it is not necessary to examine the inventive step of its dependent claims.

5.09 Otherwise, if the independent claim does not have an inventive step, its dependent claims must be examined, since they may contain specific elements that make that matter inventive.

§II. STEPS FOR EXAMINING AN INVENTIVE STEP

5.10 Three stages are adopted to determine whether a claimed invention is obvious when compared with state of the art:

- i. to determine the closest state of the art;
- ii. to determine the different characteristics of the invention and/or the technical problem in fact solved by the invention; and
- iii. to determine whether the invention is obvious or not for person skilled in the art.

DETERMINING THE CLOSEST STATE OF THE ART

5.10.1 The closest state of the art consists of one or two documents, or exceptionally three, related to the claimed invention in each independent claim, and should be the basis for assessing the presence of an inventive step. The closest state of the art may be as follows:

Example¹: *An existing technology in the same technical field as that of the claimed invention, in which the technical problem to be solved, technical effects or intended use are closest to the claimed invention; or it describes the largest number of technical characteristics of the claimed invention.*

Example²: *An existing technology that, in a different technical field from the field of the claimed invention (see item 5.4 herein), is able to act as an invention, and describes the largest number of the technical characteristics of the invention.*

5.10.2 The closest state of the art should be measured from the perspective of person skilled in the art on the relevant date of the application.

5.10.3 It must be noted that, when determining the closest state of the art, the state of the art from the same field or similar field as the invention must be considered first.

DETERMINING THE DIFFERENT CHARACTERISTICS OF THE INVENTION AND THE TECHNICAL PROBLEM SOLVED BY THE INVENTION

5.10.4 The examiner should objectively analyze and determine the technical problem solved by the invention. Thus, the examiner should first determine the different characteristics of the claimed invention in comparison with the closest state of the art, and assess whether person skilled in the art could easily reach this result, or still optionally determine the technical problem that is, in fact, solved by the invention.

5.10.5 Bearing in mind that the closest state of the art identified by the examiner may differ from that presented by the applicant in the specification, the technical problem actually solved by the invention may not be the same as that described in the report.

5.10.6 In such a circumstance, the technical problem actually solved by the invention must be reformulated based on the closest state of the art identified by the examiner.

5.10.7 In principle, any technical effect of an invention may be used as basis for reformulating the technical problem, provided that the technical effect can be recognized by person skilled in the art, from what is presented in the specification.

5.10.8 In the case of results/tests/essays or similar presented during the technical examination – after the examination application, in order to prove the technical effect of the invention, the presentation of such data in the applicant's argument should be inherent to the matter first disclosed. In such cases, the technical effect of the invention should be described in the first disclosed matter, although not quantitatively.

5.10.9 In cases where these *result/test/essay* or *similar* data deal with an undisclosed technical effect and also inherent in the originally deposited application, such information shall be disregarded in the assessment of the invention's technical effect.

5.10.10 Characteristics that do not contribute individually or jointly with other characteristics to the technical character of the invention are not considered for inventive step assessment. This situation may occur if a characteristic contributes only to the solution of a non-technical problem, such as a problem in a field excluded by article 10 of the Brazilian IP Statute.

Example: Consider a cup characterized by design X. Design X does not have any technical effect, but merely *aesthetical*. In this case the assessment of an inventive step must be concerned solely with cups, regardless of the design, which is disregarded.

5.10.11 It should be noted that the objective technical problem must be formulated in order not to contain any references to the technical solution, since, when including part of the technical solution offered by the invention in

defining the problem, the examiner may be induced to conclude that the invention does not have an inventive step.

Example: *A vehicle has brake lights positioned outside the line of vision of the driver of another vehicle following behind the first, which may help cause collisions. Consider that the technical problem was defined because of the lack of alignment between the first vehicle's brake lights and the line of vision of the driver of the second vehicle, and that the solution to the problem consists of raising the position of the brake lights to align them properly. The presence of part of the solution - alignment - when defining the problem could induce the examiner to conclude the lack of an inventive step. In this case, the technical problem would be best defined by "difficulty in warning the second vehicle about the first vehicle's brakes".*

DETERMINING WHETHER THE INVENTION IS OBVIOUS FOR THE PERSON SKILLED IN THE ART

5.10.12 At this stage, the examiner should judge, based on the closest state of the art and the proposed solution for the technical problem, whether the invention is obvious or not for person skilled in the art. During the judgment, what should be determined is whether there is motivation to apply said different characteristics in the invention to the closest state of the art in order to solve the existing technical problem.

5.10.13 Person skilled in the art should not be considered a mere automaton motivated only by the content disclosed in the documents, but as someone endowed with a minimum of creativity and discernment. If the state of the art information, plus the knowledge and experience attributed to the person skilled in the art, lead him to improve the closest state of the art in order to reach the claimed invention, the invention is considered obvious. It should be analyzed whether any teaching in state of the art, overall, would necessarily lead person skilled in the art, given the technical problem, to modify or adapt the closest state of the art, in order to achieve the solution proposed by the claim.

§III. COMBINATION OF STATE OF THE ART DOCUMENTS

5.11 When determining whether the combination of two or exceptionally three different disclosures result in obvious or not, the examiner shall adopt the following criteria:

- i. if the content of the documents is such that person skilled in the art would be able to combine them given the problem solved by the invention; and
- ii. if the documents come from similar or close technical fields, and otherwise, if the documents belong to a particular problem to which the invention is related;
- iii. the combination of two or more parts of the same document may be obvious if there is a reasonable basis for person skilled in the art to associate these parts with each other.

SPECIFIC SITUATIONS IN ASSESSING INVENTIVE STEP

§I. INVENTION THAT OPENS UP A NEW FIELD

5.12 An invention that opens a new field involves an inventive step. Below are some examples of these revolutionary inventions:

Examples: *Compass, paper, printing technique, gunpowder, steam engine, filament lamp, radio, radar, fiber optics and laser.*

§II. INVENTION BY COMBINATION

5.13 An invention by combining elements refers to a new solution of a technical problem, obtained by combining certain state of the art solutions.

5.14 When determining the inventive step of an invention by combination, the following factors must usually be considered:

- i. if the combined technical characteristics integrate functionally;
- ii. if there is difficulty or facility in the combination;
- iii. if there is any motivation to achieve the combination; and
- iv. the technical effect resulting from the combination.

5.15 It is not necessary to explicitly find in state of the art some suggestion, motivation or teaching for a combination of known documents. Motivation may even be in another branch of the technique and refer to another problem, or person skilled in the art, endowed with good common sense and creativity, can be motivated to achieve this combination.

OBVIOUS COMBINATION

5.15.1 If a claimed invention is merely be an aggregation or juxtaposition of certain known elements, each functioning in its routine form, and the total technical effect is only the sum of the technical effects of each part with no synergy or functional interaction between the combined technical characteristics, then the invention by combination does not involve an inventive step.

Example: *The invention refers to a ballpoint pen with electronic watch, where the solution is merely to fix a known electronic watch to a known ballpoint pen. After the combination, the electronic watch and ballpoint pen still function as normal, with no working interaction between them and, thereby, the invention is only a mere aggregation and does not involve an inventive step.*

5.15.2 Moreover, if the combination involves the scope of the normal development of technology, with no unexpected technical effect, then the invention does not involve an inventive step.

5.15.3 On the other hand, if the documents indicated as prior art directly mention that the solution proposed in the application under analysis should not be followed by person skilled in the art, that is, the prior art suggests that the person skilled in the art departs from the solution proposed in the application under analysis, it is clear that person skilled in the art is not motivated to use such documentation to reach the proposed solution, which is evidence of an inventive step. In this case, the technical precept present in the prior art would remove person skilled in the art from the found solution.

NON-OBVIOUS COMBINATION

5.15.4 If the combined technical characteristics functionally interact with each other and produce a new technical effect or, in other words, if the technical effect, after the combination, is different from the sum of the technical effects of the individual characteristics, then such a combination has an inventive step. The fact that any of the

technical characteristics itself in the invention by combination is known does not compromise the inventive step of said invention.

Example: *The technical effect of an individual transistor is essentially an electronic switch. However, interconnected transistors in order to form a microprocessor interact synergically to achieve technical effects, such as data processing. Accordingly, the technical effects go beyond the sum of its respective individual technical effects.*

§II. INVENTION BY SELECTION

5.16 When checking the inventive step in selection patents, it should be borne in mind that the selected element(s) or subrange must compose an independent invention and/or new learning, and not a mere arbitrary selection from the state of the art.

5.17 If it is found that a specific member of the general group of state of the art also has already such a characteristic, the selection will not have an inventive step. The mere choice of arbitrary elements/subgroups/subranges does not guarantee the attribution of an inventive step for the selection, as the effects/properties arising from such a choice will always be assessed from the viewpoint of person skilled in the art. It is emphasized that supplementary data are acceptable for confirmation of an inventive step.

OBVIOUS SELECTION

5.17.1 The following cases correspond to an obvious selection:

- i. If the invention consists merely of choosing among a number of known possibilities or merely choosing a number of equally possible alternatives, and the selected solution does not produce any unexpected technical effect, the invention does not involve an inventive step.

Example: *In state of the art many heating processes are described, when the invention lies in selecting a known process, namely, electric heating for a chemical reaction that requires heating, if the selection does not produce any unexpected technical effect, the invention does not involve an inventive step.*

- i. If the invention lies in choosing particular dimensions, temperature ranges or other parameters based on a limited range of possibilities, if such a choice could be made by person skilled in the art through normal design procedures and not produce any unexpected technical effect, the invention does not involve an inventive step.

Example: *The invention refers to a process for achieving a known reaction and is characterized by a specific rate of flow of an inert gas. If person skilled in the art determines the rate of flow by conventional calculation then the invention does not involve an inventive step.*

- i. If the invention can be obtained by mere direct extrapolation from the state of the art, it does not involve an inventive step.

Example: *The invention consists of increasing the heat stability of a Y compound characterized by using a specific minimum quantity of an X compound in the Y composition, while, in fact, the specific minimum quantity of the X*

compound can be derived from the ratio curve between the quantity of the X compound and the heat stability of the Y composition. Thus, the invention does not involve an inventive step.

NON-OBVIOUS SELECTION

5.17.2 The following cases correspond to a non-obvious selection:

- i. When the invention involves a special selection of particular operational conditions, such as temperature and pressure in a process, within a known range, and such selection produces unexpected technical effects in the functioning of the process or properties of the resulting product.

Example: A process in which the substances A and B are transformed at high temperatures into substance C, is known as a process between 50oC and 130°C, with illustrative examples using temperatures of 110oC and 125oC. It is now determined that in the temperature range of between 63°C and 65°C, which has not been previously explored, the yield of substance C was considerably higher than expected and with a higher degree of purity.

- i. The invention consists of selecting certain chemical compounds or compositions – including alloys, from a wide field, where these compounds or compositions have an unexpected technical effect.

Example: The invention lies in selecting a radical “R” of a set of possibilities defined in state of the art (commonly in a Markush formula). The selected compounds have non-obvious properties, without any sign that they would induce person skilled in the art to make this selection in particular. Generally, such effects are confirmed by submitting comparative tests.

- i. If the invention is obtained from a selection that produces an unexpected technical effect, the invention has an inventive step:
 - a) In cases where the parameters vary and the state of the art does not give indications about the more critical parameters to be tested or about the more promising possibilities; and
 - b) In cases of exploring a new technology that is a promising field of investigation but whose state of the art only has general indications about the possibilities of the invention.

Example: In a document of state of the art that describes the production of an acid, the catalyst proportion for one (1) mol of raw material is more than 0 and equal to 100% (mol) or less. In the given example, the quantity of catalyst is 2% to 13% (% molar), and it is indicated that the productivity begins to increase from 2% of the catalyst quantity. Moreover, person skilled in the art considers the increase in the catalyst quantity in order to increase productivity. In an invention by selection referring to a process for producing the aforementioned acid, a smaller quantity of catalyst (0.02% to 0.2%) is used. However, productivity increases 35%, far exceeding the expected productivity and, furthermore, the processing of the reagent is also simplified. All this shows that the selected technical solution for this invention produced unexpected technical effects, since from the previous conclusions, person skilled in the art would have been led to increase the catalyst quantity to improve the productivity of the process, and not reduce it and, therefore, the invention involves an inventive step.

§IV. INVENTION BY ANALOGY OF A TECHNICAL FIELD

5.18 Invention by analogy of a technical field refers to an invention that applies a known technology in one technical field applied to another technical field.

5.19 One skilled in the art may be led to look for suggestions in other like or remote technical fields. The investigation done by the examiner if the solution involves an inventive step must be based on the knowledge and skill of person skilled in the art.

5.20 When determining the inventive step by analogy of a technical field, usually the following factors need to be considered: proximity between the two technical fields; if there is corresponding technical motivation; the level of difficulty in adapting the known technology to the other technical field; any technical difficulties to be overcome; and the achieved technical effect.

5.21 If the technical field analogy is made between similar or proximate technical fields and no unexpected technical effect is obtained, the invention does not involve an inventive step.

Example: *Application of a support structure for a cupboard to carry a table does not involve an inventive step.*

5.22 If the technical field analogy produces an unexpected technical effect overcoming difficulties found in the state of the art, then the invention has an inventive step.

Example: *The invention refers to submarine ailerons. In state of the art, a submarine stays in an arbitrary place underwater because of the balance between its dead weight and buoyancy of the water, and rises by horizontal operation of the cabin to increase buoyancy. In a remote technical area, such as aeronautics, an airplane flies using the thrust of the air produced completely by its main wings. The invention uses the technical measures applied to aircraft and applies the idea of the main wings of the airplane to the submarine. As a result, under the forces of thrust or submersion created by the mobile flaps acting as the submarine's ailerons, the rise and fall performance of the submarine is considerably improved. Bearing in mind that many technical difficulties were overcome when applying aircraft technology to underwater technology, the invention produces unexpected technical effects and involves an inventive step.*

§V. INVENTION OF A NEW USE (NON-MEDICAL) OF A KNOWN PRODUCT

5.23 An invention of a new use of a known product refers to the invention that uses a known product for a new purpose.

5.24 When determining the inventive step of an invention of a new use of a known product, usually the following factors should be considered: the proximity of the technical field of the new use with the prior use and unexpected technical effect of the new use.

5.25 If the new use merely utilizes a known property of a known material, the invention of a new use does not involve an inventive step.

Example: *The use of a known composition such as material cutting aid (new use), in which the state of the art uses it as a lubricant, does not involve an inventive step.*

5.26 If the new use adopts an observed property in a known product and can produce an unexpected technical effect, then the invention of use thereby presents an inventive step.

Example: *The use of a composition such as herbicide, in comparison with the use as a timber preservative disclosed by state of the art, produces an unexpected technical effect and, therefore, involves an inventive step.*

§V. INVENTION BY ALTERATION OF ELEMENTS

5.27 Inventions by altering elements include inventions that alter ratios between elements, inventions that substitute elements, and inventions that omit elements.

5.28 When determining the inventive step of an invention by altering elements, usually the following factors need to be considered: if there is technical motivation for altering the ratios between elements or to substitute or omit elements, and if the technical effect would be expected.

INVENTION BY ALTERATION OF RELATIONS BETWEEN ELEMENTS

5.28.1 An invention by altering ratios between elements means that, when compared to state of the art, the format, size, proportion, position, operating relation, alteration of the order of stages in a method, or similar, was altered.

5.28.2 If the alteration in ratios between elements does not lead to an alteration on the effect, function or use of the invention, or the alteration of the effect, function or use of the invention can be expected, the invention does not involve an inventive step.

Example: *In the state of the art a measuring instrument is described containing a fixed dial and rotary handle, and the invention is a similar measuring instrument, but containing a fixed handle and rotary dial. The difference between the invention and state of the art lies only in altering the ratio between the elements; in other words, the reversal between motion and immobility. This type of reversal produces no expected technical effect whatsoever and, therefore, the invention does not involve an inventive step.*

5.28.3 If an alteration to ratios between elements produces an unexpected technical effect, the invention has an inventive step.

Example: *The invention refers to a grassmower that is characterized by the fact that the oblique angle of its blade is different from that of a traditional grassmower; that is, the oblique angle of the invention enables the blade to be automatically sharpened, while the angle of the blade in the state of the art has no such effect. The invention produces an unexpected technical effect by altering elements and, therefore has an inventive step.*

INVENTION BY SUBSTITUTION ELEMENTS

5.28.4 An invention by substituting elements refers to an invention that is obtained by substituting a certain known element of a product or process by another element.

5.28.5 The invention does not involve an inventive step when, in solving the same technical problem, a substitution is made of a known element by another with the same function to obtain predictable results, that is, without observing any unexpected technical effect.

Example¹: *The invention refers to a pump that differs from state of the art in the fact that the driving force in the invention is provided by an electric instead of hydraulic engine. In this case, the electric engine operates in the same way as the hydraulic and, therefore, achieves a predictable effect.*

Example²: *The invention refers to an aluminum car chassis, where the state of the art uses steel for this same chassis. In this case, the technical effect referring to reducing weight is predictable, since it is an inherent property of aluminum.*

5.28.6 If the substitution of elements produces an invention, then the invention has an inventive step.

Example: *The state of the art refers to a process containing steps A, B, C and D, and the invention substitutes stage C with a functionally similar stage but that surprisingly improves the output of the process.*

INVENTION BY OMISSION ELEMENTS

5.28.7 An invention by omitting elements refers to an invention in which one or more elements of a known product or process are omitted.

5.28.8 If, after omitting one or more elements, the corresponding function disappears as a result, or if such omissions are obvious for person skilled in the art, the invention does not involve an inventive step.

Example: *The invention of a paint composition differs from the state of the art in the fact that it does not include an antifreeze agent. If the antifreeze effect of the paint composition is lost as a result of omitting the antifreeze agent, the invention does not involve an inventive step.*

5.28.9 If, when comparing the state of the art, after omitting one or more elements (either elements of a product or stages in a process), which may be associated with reformulating the invention, and the technical effects are preserved or enhanced, then the invention has an inventive step.

Example: *State of the art addresses a process for manufacturing an alloy used in a cylinder head, where one of the stages in this process is heat treatment of the alloy. An invention that addresses a process for manufacturing an alloy to be used in a cylinder head alters the chemical composition of the alloy, making the heat treatment stage unnecessary, presents an inventive step, since the final result has been preserved.*

SECONDARY FACTORS TO BE CONSIDERED UPON EXAMINING AN INVENTIVE STEP

5.29 The elements considered in the §§ herein above consist of the main criterion for assessing the requirement of an inventive step. In many cases, however, they are not enough to reach a safe conclusion about the presence of the requirements, so some signs may then be considered, indicative of the inventive step. It should be emphasized, however, that such secondary signs are important only in case of doubt, when the objective examination of prior art teachings does not result in a clear enough conclusion.

§I. SOLUTION OF A LONG-KNOWN BUT UNSOLVED TECHNICAL PROBLEM

5.30 When an invention has solved a technical problem that has long been awaiting a solution, but in vain, the invention could feature an inventive step.

Example: Branding domestic animals such as cattle without causing pain to them or damage to the animal's skin has been an age-old problem since the beginning of livestock farming. An inventor successfully solved this technical

problem with a cold branding solution based on the discovery that the skin can be permanently pigmented by freezing, without causing pain to the animal. This solution can involve an inventive step.

§II. OVERCOMING PRECONCEPTION OR TECHNICAL BARRIER

5.31 Overcoming prejudice or a technical obstacle or the proof that the invention adopted a way contrary to knowledge consolidated by state of the art can reinforce an allegation of the presence of an inventive step.

Example: *It has generally been believed that in an electric motor the smoother the interface of the switch with the brush, the better the contact would be and less current consumption. The invention produces rough microgrooves on the surface of the switch, and the current consumption is even lower than with a smooth surface. Bearing in mind that the solution overcame the technical preconception, it can feature an inventive step.*

§III. ACHIEVING COMMERCIAL SUCCESS

5.32 When an invention is commercially successful, such as, technology licensing, if this success is directly related to the technical characteristics of the invention, this could mean that the invention features an inventive step. However, if the success is due to other factors, such as advertising or sales campaigns, this criterion must not be used as a basis for assessing the inventive step.

§IV. WINNING AWARDS

5.33 When an invention is awarded with some kind of recognition for its technical merit, this could mean that the invention features an inventive step.

Example: *Prize or honorable mention in conferences.*

§V. HOW THE INVENTION IS CREATED

5.34 How an invention is created, irrespective of how hard or easy it is, should not affect the assessment of its inventive step. The majority of inventions is the result of the inventor's creative work and outcome of scientific research and long-term work experience, although some inventions are created by accident.

Example: *Motor vehicle tires have high mechanical and good abrasion resistance. This was achieved by a technician who made a mistake by adding 30% instead of 3% carbon when preparing materials for the production of black rubber. The facts show that the rubber with 30% carbon has high abrasion-resistance, which was not expected beforehand. Although the invention was created by accident, this should not be taken into account when assessing the inventive step.*

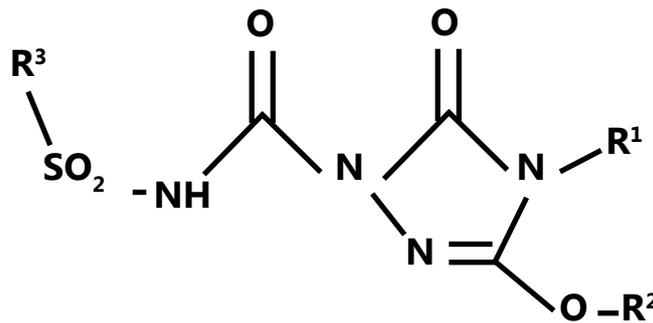
CHAPTER VI. MARKUSH FORMULAS

INTRODUCTION

6.01 Markush formulas are a way to describe and claim various alternatives in patent applications. Although this is more common in the chemistry and biotechnology fields, the presentation of alternatives for inventions in any technical field can be considered a Markush formula. The use of this resource goes back to an American patent in

1924 by Eugene A. Markush, presenting alternatives within a dyestuffs manufacturing process.

6.02 The “Markush formula” is a general expression for a class of chemicals, conventionally used in patents, and consists of a basic chemical structure that is substituted by one or more variable substructures, accompanied by a list of definitions of these variable portions, wherein: R¹ represents H, OH, amino; R² represents H or CH³; and R³ represents a radical of the groups of substituents that consists of alkyl (between 1 and 6 carbons), phenyl and pyridine, as shown in the following figure:



6.03 Thus, the term “Markush formula” has been used for any chemical structure containing a basic structure and one or more optional or variable chemical groups. For biological sequences, it is possible to delimit the basic sequence of nucleotides or amino acids and the alternatives provided in various positions.

6.04 A Markush formula enables the choice of a large number of substitutes, which can be linked to the molecule in different positions, as well as through their different arrangements. Consequently, multiple compounds can be protected by a single representation structure.

NOVELTY

6.05 Any unexpected change in a Markush formula in the state of the art leads to a new compound, thereby meeting the novelty requirement.

Example: *When there is an invention that described a compound with a basic structure of a heterocyclic ring with a propyl substituent group, and the technique describes another compound with the same heterocyclic basic structure with a methyl substituent group in the same position; the propyl and methyl groups, although belonging to the same chemical class – alkyl with 1 to 6 carbon atoms, do not take away the novelty of the invention.*

6.06 It should be stressed that, due to the many possibilities of compounds foreseen in a Markush formula, the analysis of the claimed matter may indicate that some of the compounds do not feature novelty, while others do.

INVENTIVE STEP

6.07 When assessing an inventive step of a Markush formula, it should be checked whether it is an evident or obvious result of state of the art. The compounds defined in the new Markush formula will present an inventive step if, based on the knowhow contained in the state of the art, person skilled in the art would not be motivated to make the proposed structural modifications. In cases where state of the art presents very similar matter to the claimed

one, the claimed compounds will present an inventive step if there is an unexpected technical effect resulted from their structural modification.

6.08 In the specific case of medicines, there may be an unexpected technical effect.

Example: *Reduction or elimination of a side effect that must be prevented.*

6.09 To prove the technical effect, it may be necessary to present comparative tests between the effects caused by the claimed compounds and those of state of the art, in order to prove the presence of an unexpected technical effect.

SUFFICIENCY OF DISCLOSURE

6.10 The description of the modus operandi of an invention is only satisfactory if it enables the invention to be performed throughout the claimed scope, and not only in some alternatives belonging to the claim. In the case of compounds defined in a Markush formula, it may not be predicted or extrapolated that the compounds with substituents belonging to different chemical classes can be obtained from the same method of preparation, since the nature of the reactions is different. Thus, for all compounds of a Markush formula to be sufficiently described, specification must present a detailed description of the reactions and conditions involved in the preparation processes, including concrete examples of preparation of at least one representative compound for each chemical class of the different substituents. In this way, the specification must provide clear examples of how different substituents provided in the Markush can be included in the final product.

6.11 If preparation of the compounds and, consequently, the actual compounds with substituents belonging to different chemical classes is not sufficiently described in the specification, it will not be possible for person skilled in the art to reproduce them, being in conflict with the provision in article 24 of the Brazilian IP Statute.

Example: *The specification refers to the alkyl substituent and the heterocyclic substituent in a certain position of the Markush formula; there may be a justifiable doubt whether the compound containing heterocyclic radicals in the same position can be obtained by the same preparation process. Therefore, this group of heterocyclic substituents – for which no preparation examples are given – would not be sufficiently described; since it cannot be assumed that the same preparation method of the chemical classes in the example can be applied to those whose preparation was not described.*

6.12 Therefore, when the examples do not include all chemical classes of the claimed compounds, the examiner shall submit an objection pursuant to article 24 of the Brazilian IP Statute.

SUPPORT, CLARITY AND PRECISION OF THE CLAIMS

6.13 It is necessary for all possible substituents claimed in the compounds to be based on the specification and be defined clearly and precisely.

6.14 An application that presents compound X in the specification and compound “X” in the claim chart, not mentioned in the specification, shows a lack of support as provided in article 25 of the Brazilian IP Statute. In such cases, generally the inclusion of compound X’ in the specification rarely includes sufficiency of disclosure to the application, being in conflict with the provision in article 24 of the Brazilian IP Statute, although it meets the support criterion as provided in article 25 of the Brazilian IP Statute.

6.15 Terms cannot be used that incur lack of definition of the matter to be patented, which must be defined as far as possible, during the examination process.

Examples: “Carbocyclic aryl”, “heterocyclic aryl”, “biaryl”, “lower alkyl”, “cycloalkyl”, and “substituted” are some expressions that imply lack of definition and precision, in claims of Markush compounds.

6.16 When the substituents are presented in this way, important characteristics are not defined, such as chain size, number and nature of heteroatoms, presence or not of branching; they only indicate to which chemical group the compounds belong.

CHAPTER VII. COMPOSITIONS

7.01 Composition is a mix of elements or chemical and/or biological components for a certain purpose, which may be present in the claim, provided that it is clear enough to prevent ambiguities.

Example: *Detergent composition characterized by containing the elements A, B and C.*

7.02 A check should be made, according to what is presented in the specification, on which characteristics shall be present in the composition claim(s) in question, in order to accurately define the claim.

7.03 On the other hand, a composition claim defined by only one component and without quantitative delimitations is equal to a claim for the component itself, inasmuch as it includes the possibility of the “composition” containing 100% of the component in question. Thus, it should be checked, according to that presented in the specification, which characteristics shall be present in the composition claims in question, in order to accurately define and delimit the rights granted to what in fact has been developed.

7.04 This means that a composition can be perfectly characterized by the presence of only one ingredient, provided that it is verified that this has been the development undertaken and that there are text elements in the claim that determine that, in fact, it is a composition. In other cases, the composition will need more accurate details for its definition.

NOVELTY

7.05 The compositions not included in state of the art are considered as new. The composition containing already known component(s) of the state of the art will be considered new if they present characteristics, such as, other components and a ratio between the components that differentiate it from state of the art.

7.06 The effect, use or administration application method does not grant novelty to a composition already known in the state of the art. However, these elements are acceptable in the text of claims to give clarity and accuracy to the claimed matter.

Example: *A “pharmaceutical composition characterized by containing X and Y” does not have novelty in relation to a document of the state of the art that addresses a detergent composition characterized by containing X and Y.*

7.07 In the case of applications for new chemicals and/or biological products that contain a composition claim, it is considered that the novelty and inventive step of the product(s) will be extended to the composition containing them.

CLARITY AND ACCURACY

§I. REQUIREMENT FOR QUALITATIVE/QUANTITATIVE DEFINITIONS

7.08 Qualitative and/or quantitative definitions, to a greater or lesser degree of accuracy, will only be required when clarity and precision of the claim are essential.

Example: *Cosmetic composition where the invention consists of adding a dye.*

7.09 Situation 1: The specification shows that the invention in fact lies in the use of a dye in cosmetic compositions, and state of the art discloses that such an addition was unknown. In this case, an acceptable claim would be: “Cosmetic composition characterized by comprising a dye associated with one or more cosmetically active ingredients”.

7.10 Situation 2: The specification shows that the invention in fact lies in the use of the dye and can be applied to any cosmetic composition. However, it is found that either the invention is not applicable to any dye (or class of) or the state of the art discloses that such an addition is already known for certain dyes (or class of). In this case, the acceptable claim shall be:

“Cosmetic composition characterized by comprising this and that dye (or class of dyes) associated with one or more cosmetically active ingredient (or other text that implies the existence of one more component)”.

7.11 Situation 3: The specification shows that the invention in fact lies in the use of the dye and is applicable to any cosmetic composition. However, it is found that the invention applies only to a certain concentration range of the dye. In this case, the acceptable claim shall be:

“Cosmetic composition characterized by comprising from x% to y% of a dye associated with one or more cosmetically active ingredient (or other text that implies the existence of one more component)”.

7.12 Situation 4: The specification shows that the invention in fact lies in the use of the dye, but that the development was focused on a certain cosmetic composition with well-defined active and non-active elements (even if at class level), including in its ranges of concentration. In this case the claim shall contain all these defined elements (qualitatively and quantitatively) according to what the examiner deems sufficient for clarity and precision of the claim.

TYPES OF COMPOSITION

§I. COMPOSITIONS DEFINED SOLELY FOR THEIR USE, ADMINISTRATION METHOD OR ACTION MECHANISM

7.13 Claims of these categories are not precise, causing a lack of definition regarding the patented matter, and should be rejected pursuant to article 25 of the Brazilian IP Statute.

7.14 Claims eligible for protection:

Example¹: *Immunogenic composition characterized in that its use induces an immunological response against the antigen.*

Example²: *Veterinary composition characterized in that it is for intramuscular administration, being the composition characterized by its form of application.*

Example³: *Composition characterized for treating asthma, the composition being defined by its therapeutic application.*

Example⁴: *Composition characterized as a serotonin-reuptake inhibitor, the composition being characterized for its action mechanism.*

Example⁵: *Pesticide composition characterized for being used as an application in soy and cotton crops.*

§II. KIT INCLUDING COMPOSITIONS

7.15 The components or groups of components in these kits are physically separated, being packed together or separately.

Example¹: *Kit comprising a vaginal cream and applicator.*

Example²: *Kit comprising a composition for treating asthma and a nebulizer.*

Example³: *Kit for flu treatment comprising one decongestant tablet and a antipyretic tablet.*

Example⁴: *Kit comprising amoxicillin powder for reconstitution and an ampoule of liquid for injection.*

Example⁵: *Adhesive kit, comprising an adhesive composition and hardening composition.*

7.16 In such cases, the way in which the claim is defined should be closely observed: If only the groups of components are defined, even if it is mentioned that they can be packed together or separately, they are patentable; and if the components and the specific form of administration are defined (certain time intervals, by parenteral, oral administration, for example). In this case, it is necessary to decide, on the study of the specification and state of the art, if the withdrawal of the form of application is possible, that is, without implying undue mutilation or extension of the patent.

§III. PRODUCT INCLUDING COMPOSITIONS CHARACTERIZED BY THEIR PHYSICAL SHAPE AND/OR FORM OF APPLICATION

7.17 A product including a composition can be claimed for its physical shape.

Example: *In the shape of a poultice, pellet, gel, aerosol, granules, pill, tablet, solution and suppository.*

7.18 A product including a composition can be claimed for its form of application.

Example: *Intravenous, subcutaneous and sublingual.*

7.19 In these cases, in addition to defining the components of the composition itself, the presence in the text of the claim of the constructive characteristics is essential.

Example: *Format, thickness, grading and type of coating of the product .*

7.20 Included here are all considerations made above in relation to the other compositions.

7.21 Thus, a claim of “Composition characterized for being in pill form”, solely defined by its physical shape, should be rejected, since it does not precisely define the patented object. Note that, in this case, protection would revert to each and any composition in pill form. However, if the composition is defined specifically and in detail regarding its components, the claim could be granted.

Example: *Composition consisting of X, Y and Z characterized by being in pill form.*

§IV. COMBINATION OF ACTIVE INGREDIENTS

7.22 A combination is the association of two or more active ingredients in the form of a product. The combination can be contained in one form only or separate forms for simultaneous administration.

7.23 Concerning the novelty requirement for a combination, the same comments apply as for compositions in general.

7.24 A combination has an inventive step whenever, for person skilled in the art, it does not evidently or obviously result from state of the art. In this case, it should be noted whether the interaction between the associated active substances in the combination produces an unexpected technical effect, other than planned, for example, a synergic or supra-additive effect, in which it does not correspond to the mere sum of the individual effects of each active substance that forms the association (additive effect), reduction in undesirable effects and so on.

7.25 However, the existence of a synergic effect does not necessarily grant an inventive step to the invention, since it could already be expected for a certain class of compounds.

SYNERGIC (OR SUPRA-ADDITIVE) EFFECT

7.26 The synergic effect is a response obtained from the association of two or more active ingredients, the outcome of which is greater than that presented by the mere sum of the effects when considered individually.

Example: *Chimeric promoter; synergy.*

7.27 Claim: Chimeric promoter consisting of the fusion of promoter A and promoter B.

The application describes a chimeric promoter consisting of the fusion of two promoters already known in state of the art. The results presented demonstrate that the expression of a gene X controlled by the chimeric promoter was superior to the expression of gene X controlled by the promoters separately or added together.

7.28 Compositions involving components with synergic effect can only be characterized qualitatively (without specifying the quantities of each component), provided that:

- i. a combination of already known products for the same application in any proportions has not been foreseen in the state of the art;
- ii. a synergic effect is clearly demonstrated; and
- iii. a synergic effect may be observed in any proportion of the products involved.

Example: *Agricultural composition.*

7.29 Claim: Synergic composition characterized by containing compound A + compound B.

The application describes a herbicide composition constituted of compounds A and B, to combat weeds in cereal crops. Both compounds separately are already known in the state of the art, but not combined.

The results of the composition were presented for various contents of both compounds and they clearly show the synergic effect, since it was superior to the herbicide action of the two compounds separately or added together.

7.30 Therefore, if any condition defined herein above is not fulfilled, the claims should be defined quantitatively, clearly specifying which are the desired proportions of the components present, limited to those that are supported in the specifications. Comparative data should be submitted in relation to the effect of the components separately and their combination, so that all tests referring to the comparative data should be performed under the same conditions.

7.31 In cases where the state of the art already consists of compositions that contain the components of interest, even though no synergic effect between them has been observed/described, or even if there is evidence of incompatibility in the broad range of concentration claimed, the claims should be defined qualitatively and quantitatively, clearly specifying which are the desired proportions of the components present, limited to those supported in the specification.



Rio de Janeiro • Rua da Assembleia, 10/4108 20011-901 Brazil
T + 55 21 3550 3700 | F + 55 21 3550 3777 | info@lickslegal.com

Sao Paulo • Rua George Ohm, 230 - A/112 04576-020 Brazil
T + 55 11 3033 3700 | F + 55 11 3033 3777 | info@lickslegal.com

Tokyo • Chiyoda Kaikan Bldg, 6F 1-6-17 Kudan Minami Chiyoda-Ku 102-0074 Japan
T + 81 3 6256 8972 | F + 81 3 6735 8982 | japan@lickslegal.com