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Brazilian Patent Statute

Statute #9,279/1996 of May 14, 1996
as amended by Statute #10,196 of February 24, 2001

Patents, utility models, industrial designs, trademarks, geographical indications and unfair competition.
Preliminary Provisions

Article 1. This statute regulates rights and obligations relating to industrial property.

Article 2. The protection of rights relating to industrial property, taking into account the interests of society and the technological and economic development of the country, is effected by means of:
I. the grant of patents of invention and utility model patents;
II. the grant of industrial design registrations;
III. the grant of trademark registrations;
IV. the repression of false geographical indications; and
V. the repression of unfair competition.

Article 3. The provisions of this statute also apply:
I. to an application for a patent or registration originating from abroad and filed in this country by a person having protection guaranteed by a treaty or convention in force in Brazil; and
II. to nationals or persons domiciled in a country that guarantees reciprocity of identical or equivalent rights to Brazilians or persons domiciled in Brazil.

Article 4. The provisions of treaties in force in Brazil are applicable, in equal conditions, to natural and legal persons that are nationals or domiciled in this country.

Article 5. For all legal effects, industrial property rights are considered to be chattels.

I. PATENTS

Chapter I. Ownership

Article 6. The author of an invention or of a utility model will be assured the right to obtain a patent that guarantees to him the property, under the terms established by this statute.

¶1. In the absence of proof to the contrary, the applicant is presumed to have the right to obtain a patent.
¶2. A patent may be applied for by the author, his heirs or successors, by the assignee or by whomever the law or a work or service contract determines to be the owner.
¶3. When an invention or utility model is created jointly by two or more persons, the patent may be applied for by all or any one of them, by naming and qualifying the others to guarantee their respective rights.
¶4. The author will be named and qualified, but may request his authorship not to be divulged.

Article 7. If two or more authors have independently devised the same invention or utility model, the right to obtain a patent will be assured to whoever proves the earliest filing, independently of the dates of invention or creation.
Sole ¶. The withdrawal of an earlier filing without producing any effects will give priority to the first later filing.

Chapter II. Patentability

§I. Patentable Inventions and Utility Models

Article 8. In order to be patentable, an invention must meet the requirements of novelty, inventive step and industrial application.
**Article 9.** An object of practical use, or part thereof, is patentable as a utility model, when it is susceptible of industrial application, presents a new shape or arrangement and involves an inventive act that results in a functional improvement in its use or manufacture.

**Article 10.** The following is not considered invention or utility model:

I. discoveries, scientific theories and mathematical methods;
II. purely abstract concepts;
III. schemes, plans, principles or methods of a commercial, accounting, financial, educational, publishing, lottery or fiscal nature;
IV. literary, architectural, artistic and scientific works or any aesthetic creation;
V. computer programs per se;
VI. the presentation of information;
VII. rules of games;
VIII. operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body; and
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.

**Article 11.** Inventions and utility models are considered to be new when not included in the state of the art.

*¶1.* The state of the art comprises everything made accessible to the public before the date of filing of a patent application, by written or oral description, by use or any other means, in Brazil or abroad, without prejudice to the provisions of articles 12, 16 and 17.

*¶2.* For the purpose of determining novelty, the whole contents of an application filed in Brazil, but not yet published, will be considered as state of the art from the date of filing, or from the priority claimed, provided that it is published, even though subsequently.

*¶3.* The provisions of the previous ¶ will be applied to an international patent application filed in accordance with a treaty or convention in force in Brazil, provided that there is national processing.

**Article 12.** The disclosure of an invention or utility model which occurs during the twelve months preceding the date of filing or priority of the patent application will not be considered as part of the state of the art, provided such disclosure is made:

I. by the inventor;
II. by the Brazilian Patent and Trademark Office - BRPTO, by means of the official publication of a patent application filed without the consent of the inventor and based on information obtained from him or as a result of his acts; or
III. by third parties, on the basis of information received directly or indirectly from the inventor or as the result of his acts.

*Sole ¶.* The BRPTO may require the inventor to provide a declaration relating to the disclosure, accompanied or not by proof, under the conditions established in the rules.

**Article 13.** An invention shall be taken to involve inventive step when, for a person skilled in the art, it does not derive in an evident or obvious manner from the state of the art.

**Article 14.** An utility model shall be taken to involve an inventive act when, for a person skilled in the art, it does not derive in a common or usual manner from the state of the art.
**Article 15.** Inventions and utility models are considered to be susceptible of industrial application when they can be made or used in any kind of industry.

**§II. Priority**

**Article 16.** Priority rights will be guaranteed to a patent application filed in a country that maintains an agreement with Brazil or in an international organization, that produces the effect of a national filing, within the time limits established in the agreement, the filing not being invalidated nor prejudiced by facts that occur within such time limits.

- ¶1. Priority claims must be made at the time of filing, but may be supplemented within 60 (sixty) days by other priorities earlier than the date of filing in Brazil.
- ¶2. A priority claim must be proved by means of a suitable document of origin, containing the number, date, title, specification and, when they exist, claims and drawings, accompanied by a simple translation of the certificate of filing or equivalent document containing data identifying the application, the contents of which will be of the entire responsibility of the applicant.
- ¶3. If not effected at the time of filing, the proof must be presented within 180 (one hundred and eighty) days from filing.
- ¶4. For international applications filed in virtue of a treaty in force in Brazil, the translation provided for in ¶2 must be filed within the period of 60 (sixty) days from the date of entry into national processing.
- ¶5. When the application filed in Brazil is completely contained in the document of origin, a declaration by the applicant in this respect will be sufficient to substitute the simple translation.
- ¶6. When the priority is obtained by virtue of assignment, the corresponding document must be filed within 180 (one hundred and eighty) days from filing or, in the case of entry into national processing, within 60 (sixty) days from the date of such entry, consular legalization in the country of origin not being required.
- ¶7. Failure to file proof within the time limits established in this article will result in loss of the priority.
- ¶8. In the case of an application filed with a priority claim, any request for early publication must be made with proof of the priority having been filed.

**Article 17.** An application for a patent of invention or for a utility model originally filed in Brazil, without a priority claim and not yet published, will guarantee a right of priority to a later application in respect of the same subject matter filed in Brazil by the same applicant or by his successors, within the period of 1 (one) year.

- ¶1. Priority will only be accepted for subject matter that is disclosed in the earlier application and will not extend to any new matter that is introduced.
- ¶2. The pending earlier application will be considered as definitively dismissed.

**§III. Non-patentable Inventions and Utility Models**

**Article 18.** The following items are not patentable:

I. whatever is contrary to morals, good customs and public security, order and health;

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; and

III. living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements - novelty, inventive step and industrial application – provided for in article 8 and which are not mere discoveries;

**Sole ¶.** For the purposes of this statute, transgenic micro-organisms are organisms, except the whole or part of...
plants or animals, which exhibit, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by the species under natural conditions.

**Chapter III. Patent Applications**

§I. Filing of the Application

Article 19. A patent application, in accordance with the conditions established by the BRPTO, will contain:

I. a request;
II. a specification;
III. claims;
IV. drawings, if any;
V. an abstract; and
VI. proof of payment of the filing fee.

Article 20. Once presented, the application will be submitted to a preliminary formalities review and, if in due order, will be protocolled, the date of presentation being considered as the filing date.

Article 21. An application that does not formally meet the requirements of article 19, but which does contain data relating to the subject matter, the applicant and the inventor, may be delivered to the BRPTO against a dated receipt which will establish an office action requesting compliance to be met within a period of 30 (thirty) days, under penalty of return or dismissal of the documentation.

Sole ¶ Once the office action has been complied, filing will be considered to have been made on the date of the receipt.

§II. Conditions of the Application

Article 22. An application for a patent of invention must refer to a single invention or to a group of inventions so interrelated as to comprise a single inventive concept.

Article 23. An application for a utility model must refer to a single principal model that may include a plurality of distinct additional elements or structural or configurative variations, provided that technical-functional and corporeal unity of the object is maintained.

Article 24. The specification must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution.

Sole ¶ In the case of biological material essential for the practical execution of the subject matter of the application, which cannot be described in the form of this article and which has not been accessible to the public, the specification will be supplemented by a deposit of the material in an institution authorized by the BRPTO or indicated in an international agreement.

Article 25. The claims must be based on the specification, characterizing the particularities of the application and defining clearly and precisely the subject matter to be protected.

Article 26. A patent application may, until the end of examination, be divided, ex officio or on request of the
applicant, into two or more applications, provided that the divisional application:
   I. makes specific reference to the original application; and
   II. does not exceed the matter disclosed in the original application.

Sole ¶ A request for division not in accordance with the provisions of this article will be dismissed.

Article 27. Divisional applications will have the filing date of the original application and the benefit of the
priority of the latter, if any.

Article 28. Each divisional application will be subject to payment of the corresponding fees.

Article 29. A patent application which is withdrawn or abandoned will be published.
   ¶1. A request for withdrawal must be filed within 16 (sixteen) months counted from the date of filing or of
   the earliest priority.
   ¶2. Withdrawal of an earlier application without producing any effect will confer priority on the first
   later application.

§III. PROSECUTION AND SUBSTANTIVE EXAMINATION

Article 30. A patent application will be kept secret during 18 (eighteen) months counted from the date of filing or of
the earliest priority, if any, after which it will be published, with the exception of the case provided for in article 75.
   ¶1. Publication of the application may be anticipated on request by the applicant.
   ¶2. The publication must include data identifying the patent application, a copy of the specification, claims,
abstract and drawings being made available to the public at the BRPTO.
   ¶3. In the case provided for in the sole ¶ of article 24, the biological material will be made available to the public
at the time of the publication to which this article refers.

Article 31. Documents and information for aiding examination may be filed by interested parties between the
publication of the application and the termination of examination.
   Sole ¶ Examination will not be initiated prior to 60 (sixty) days from publication of the application.

Article 32. In order to better clarify or define a patent application, the applicant may effect alterations up to the
request for examination, provided that they are limited to the subject matter initially disclosed in the application.

Article 33. Substantive examination of a patent application must be requested by the applicant or by any interested
party, within 36 (thirty six) months counted from the date of filing, under penalty of dismissal of the application.
   Sole ¶ The patent application may be reinstated, on request by the applicant, within 60 (sixty) days counted from
the dismissal, on payment of a specific fee, under penalty of definitive dismissal.

Article 34. Once examination has been requested and whenever so requested, the following should be filed within
60 (sixty) days, under penalty of dismissal of the application:
   I. objections, prior art searches and the results of examination for the grant of corresponding applications in
other countries, when there is a priority claim;
   II. documents necessary to regularize the proceedings and substantive examination of the application; and
   III. a simple translation of the suitable document mentioned in ¶2 of article 16, should it have been substituted
by the declaration provided for in ¶5 of that same article.
Article 35. At the time of the substantive examination, a search report and an opinion will be prepared with respect to:
   I. the patentability of the application;
   II. the adaptation of the application to the nature of protection claimed;
   III. the reformulation of the application or the division thereof; or
   IV. technical requirements.

Article 36. When the office action is for non-patentability or for the inadequacy of the application for the nature of protection claimed or formulates any requirement, the applicant will be notified to reply within a period of 90 (ninety) days.
   ¶1. If no reply to the office action is filed, the application will be definitively dismissed.
   ¶2. If a reply to the office action is filed, but the latter is not met or its formulation is reconsidered, and independently of arguments being filed regarding patentability or adequacy, examination will be continued.

Article 37. Once examination is concluded, a decision will be issued, allowing or rejecting the patent application.

Chapter IV. Patent Grant and Term

§I. Patent Grant

Article 38. A Patent will be granted after the application is allowed and, after proving payment of the corresponding fee, the respective letters patent will be issued.
   ¶1. Payment of the fee and the respective proof thereof must be effected within 60 (sixty) days from allowance.
   ¶2. The fee provided for in this article may also be paid and proved within 30 (thirty) days after the time limit provided for in the previous ¶, independently of any notification, by payment of a specific fee, under penalty of definitive dismissal of the application.
   ¶3. The patent will be considered granted as of the date of publication of the respective act.

Article 39. The letters-patent will include the respective number, title and nature of protection, the name of the inventor, observing the provisions of article 6, ¶4, the qualification and domicile of the patentee, the term, the specification, the claims and the drawings, as well as data relating to the priority.

§II. Patent Term

Article 40. A patent of invention will have a term of 20 (twenty) years and a utility model patent a term of 15 (fifteen) years, counted from the filing date.

Sole ¶ The term will not be less than 10 (ten) years for patents of invention and 7 (seven) years for utility model patents, counted from grant, except when the BRPTO is prevented from proceeding with the examination as to the merit of the application, due to be proven pending judicial decision or for reasons of “force majeure”.

Chapter V. Protection Conferred by a Patent

§I. The Rights

Article 41. The extension of the protection conferred by a patent will be determined by the content of the claims, interpreted in the light of the specification and drawings.
Article 42. A patent confers on its proprietor the right to prevent third parties from manufacturing, using, offering for sale, selling or importing for such purposes without his consent:
I. a product that is the subject of a patent;
II. a process, or product directly obtained by a patented process;
¶1. The patentee is further guaranteed the right to prevent third parties from contributing to the practice by other parties of the acts referred to in this article.
¶2. The rights in a process patent will be violated, insofar as item II is concerned, when the holder or owner of a product fails to prove, through specific judicial ruling, that it was obtained by a manufacturing process different from that protected by the patent.

Article 43. The provisions of the previous article do not apply:
I. to acts practiced by unauthorized third parties privately and without commercial ends, provided they do not result in prejudice to the economic interests of the patentee;
II. to acts practiced by unauthorized third parties for experimental purposes, related to studies or to scientific or technological research;
III. to the preparation of a medicine according to a medical prescription for individual cases, executed by a qualified professional, as well as to a medicine thus prepared;
IV. to a product manufactured in accordance with a process or product patent that has been placed on the internal market directly by the patentee or with his consent;
V. to third parties who, in the case of patents related to living matter, use, without economic ends, the patented product as the initial source of variation or propagation for obtaining other products;
VI. to third parties who, in the case of patents related to living matter, use, place in circulation or commercialize a patented product that has been introduced lawfully onto the market by the patentee or his licensee, provided that the patented product is not used for commercial multiplication or propagation of the living matter in question; and
VII. to acts practiced by unauthorized third parties relating to the patented invention carried exclusively to produce information, data and test results to seek market approval in Brazil or abroad, in order to exploit or commercialize the patented product after the term set by article 40 has expired.

Article 44. A patentee is guaranteed the right to obtain compensation for the unauthorized exploitation of the subject matter of the patent, including exploitation that occurred between the date of publication of the application and that of grant of the patent.
¶1. If the infringer obtains, by any means, knowledge of the contents of a filed application, prior to publication, the period of undue exploitation, for the effect of compensation, will be counted from the date of commencement of the exploitation.
¶2. When the subject matter of a patent application relates to biological material, deposited under the terms of the sole ¶ of article 24, the right to compensation will only be conferred when the biological material has been made available to the public.
¶3. The right to obtain compensation for unauthorized exploitation, including with respect to the period prior to grant of the patent, is limited to the contents of the subject matter of the patent, under the terms of article 41.

§II. Prior User

Article 45. A person who in good faith, prior to the date of filing or of priority of a patent application, exploits its object in this country, will be guaranteed without onus the right to continue the exploitation, in the previous form and conditions.
1. The right conferred under the terms of this article can only be ceded by transfer or leasing, together with the business of the undertaking, or the part thereof that has direct relation with the exploitation of the subject matter of the patent.

2. The right to which this article refers will not be guaranteed to a person who had knowledge of the subject of the patent due to disclosure under the terms of article 12, provided that the application was filed within 1 (one) year from the disclosure.

**Chapter VI. Patent Nullity**

**§I. General Provisions**

**Article 46.** A patent is null when granted contrary to the provisions of this statute.

**Article 47.** Nullity may not be applicable to all of the claims, a condition for partial nullity being that the subsisting claims constitute subject matter that is patentable per se.

**Article 48.** Nullity of a patent will produce effects as from the filing date of the application.

**Article 49.** In the case of the provisions of article 6 not having been observed, the inventor may alternatively claim, in a court action, the adjudication of the patent.

**§II. Administrative Nullity Procedure**

**Article 50.** Nullity of a patent will be declared administratively when:

I. any of the legal requisites have not been met;

II. the specification and the claims do not meet the provisions of articles 24 and 25, respectively;

III. the subject of protection of the patent extends beyond the contents of the application as originally filed; or

IV. any of the essential formalities indispensable for grant were omitted during prosecution.

**Article 51.** The nullity procedure may be instituted ex officio or at the request of any person having legitimate interest, within 6 (six) months counted from the grant of the patent.

**Sole ¶** The nullity procedure will continue even if the patent is extinct.

**Article 52.** The patentee will be notified to respond within a period of 60 (sixty) days.

**Article 53.** Independently of a reply having been filed, once the period determined in the previous article has passed, the BRPTO will issue an opinion, notifying the patentee and the applicant to reply within a common period of 60 (sixty) days.

**Article 54.** Once the period determined in the previous article has passed, even if no replies have been presented, the process will be decided by the Commissioner of the BRPTO, terminating the administrative sphere.

**Article 55.** The provisions of this § apply, where appropriate, to certificates of addition.
§III. NULLITY ACTIONS

Article 56. A nullity action can be filed at any time during the term of a patent by the BRPTO or by any legitimately interested party.

¶1. Nullity of a patent may be argued, at any time, as matter for defense.

¶2. The judge may, as a preventive or incidental measure, determine the suspension of the effects of a patent, provided the relevant procedural requirements are met.

Article 57. Nullity actions will be adjudged in the forum of the Federal Courts, and the BRPTO, when not plaintiff, will participate in the action.

¶1. The period for the defendant to reply will be 60 (sixty) days.

¶2. Once the decision on a nullity action becomes res judicata, the BRPTO will publish a notice to notify third parties.

CHAPTER VII. ASSIGNMENT AND NOTATIONS

Article 58. A patent application or patent, the contents of which are indivisible, may be assigned in whole or in part.

Article 59. The BRPTO will make the following notations:

I. assignments, mentioning the complete qualification of the assignee;
II. any limitation or onus applied to the application or patent; and
III. alterations of name, headquarters or address of the applicant or patentee.

Article 60. Notations will produce effect with regard to third parties as from the date of their publication.

CHAPTER VIII. LICENSES

§I. VOLUNTARY LICENSES

Article 61. A patentee or applicant may execute a license contract for exploitation.

Sole ¶ The licensee may be invested by the patentee with all powers to act in defense of the patent.

Article 62. A license contract must be recorded at the BRPTO to produce effect with regard to third parties.

¶1. The recording will produce effect with regard to third parties as from the date of its publication.

¶2. A license contract need not be recorded at the BRPTO for it to have effect for validating proof of use.

Article 63. Any improvement to a licensed patent belongs to the person who made it, the other contracting party being guaranteed the right of preference with respect to a license.

§II. OFFER TO LICENSE

Article 64. A patentee may request the BRPTO to place his patent under offer with a view to its exploitation.

¶1. The BRPTO will promote publication of the offer.

¶2. No exclusive voluntary license contract will be recorded by the BRPTO without the patentee having withdrawn the offer.
¶3. No patent subject to an exclusive voluntary license may be made the subject of an offer.
¶4. The patentee may withdraw the offer at any time prior to the express acceptance of its terms by an interested party, whereby the provisions of article 66 will not apply.

Article 65. In the absence of an agreement between the patentee and the licensee, the parties may request the BRPTO to arbitrate the remuneration.
¶1. For the effects of this article, the BRPTO will observe the provisions of ¶4 of article 73.
¶2. The remuneration may be reviewed after 1 (one) year of it being established.

Article 66. A patent under offer will have its annuities reduced by one half during the period between the offer and the grant of the first license of any type.

Article 67. The patentee may request cancellation of the license if the licensee does not initiate effective exploitation within 1 (one) year of the grant of the license, interrupts exploitation for a period longer than 1 (one) year or, further, if the conditions for exploitation are not obeyed.

§III. Compulsory Licenses

Article 68. A patentee will be subject to have his patent licensed compulsorily if he exercises the rights resulting therefrom in an abusive manner or by means of it practices abuse of economic power that is proven under the terms of the law by an administrative or court decision.
¶1. The following may also result in a compulsory license:
   I. the non-exploitation of the subject matter of the patent in the territory of Brazil, by lack of manufacture or incomplete manufacture of the product or, furthermore, by lack of complete use of a patented process, except in the case of non-exploitation due to economic unviability, when importation will be admitted; or
   II. commercialization that does not meet the needs of the market.
¶2. The license can only be requested by a party with legitimate interest and that has the technical and economic capacity to carry out the efficient exploitation of the subject matter of the patent, that should be destined predominantly for the internal market, suppressing, in this case, the exception provided for in item I of the previous ¶.
¶3. In the case that a compulsory license is granted due to abuse of economic power, a period of time, limited to that provided for in article 74, will be guaranteed to the licensee proposing to manufacture locally, to proceed with the importation of the subject matter of the license, provided it has been placed on the market directly by the patentee or with his consent.
¶4. In the case of importation to exploit a patent and in the case of importation provided for in the previous ¶, the importation by third parties of a product manufactured according to a process or product patent will equally be allowed, provided it has been placed on the market directly by the patentee or with his consent.
¶5. A compulsory license, to which ¶1 relates, may only be requested after 3 (three) years from grant of the patent.

Article 69. A compulsory license will not be granted if, at the date of the request, the patentee:
   I. justifies non-use for legitimate reasons;
   II. proves that serious and effective preparations for exploitation have been carried out; or
   III. justifies lack of manufacture or commercialization due to legal obstacles.

Article 70. A compulsory license will also be granted when the following hypotheses are shown to exist cumulatively:
I. a situation of dependency of one patent on another is characterized;
II. the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent; and
III. the patentee does not come to an agreement with the patentee of the dependent patent for the exploitation of the earlier patent.

¶1. For the purposes of this article, a dependent patent is considered as the exploitation of which depends obligatorily on the use of the subject matter of the earlier patent.
¶2. For the purposes of this article, a process patent may be considered as dependent on a patent for the respective product, as also a product patent may be dependent upon a process patent.
¶3. The proprietor of a patent licensed under the terms of this article will have the right to a compulsory cross license under the dependent patent.

Article 71. In cases of national emergency or public interest, declared in an act of the Federal Executive Authorities, insofar as the patentee or his licensee does not meet such necessity, a temporary ex officio non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee.

Sole ¶ The act of grant of the license will establish its term of validity and the possibility of extension.

Article 72. Compulsory licenses will always be granted without exclusivity, sublicensing not being permitted.

Article 73. An application for a compulsory license must be formulated by indicating the conditions offered to the patentee.

¶1. Once the application for a license has been filed, the patentee will be notified to respond within a period of 60 (sixty) days, at the end of which, in the absence of a response from the patentee, the proposal will be considered as accepted under the conditions offered.
¶2. An applicant for a license who alleges abuse of patent rights or abuse of economic power must file documentary proof.
¶3. If a compulsory license is requested on the basis of lack of exploitation, it will rest with the patentee to prove exploitation.
¶4. If there is a request for reconsideration, the BRPTO may take the necessary steps, including the establishment of a committee that may include specialists that are not part of the BRPTO, with a view to arbitrating the remuneration that will be paid to the patentee.
¶5. The organs and entities of the direct or indirect, federal, state and municipal public administration will provide the BRPTO with such information as is requested with a view to assisting the arbitration of remuneration.
¶6. In arbitrating remuneration, the circumstances of each case will be considered, taking into account obligatorily the economic value of the license granted.
¶7. Once the process is duly filed, the BRPTO will come to a decision regarding the grant and the conditions of the compulsory license within a period of 60 (sixty) days.
¶8. Appeals against decisions granting a compulsory license will not have staying effects.

Article 74. In the absence of legitimate reasons, the licensee must initiate exploitation of the subject matter of the patent within a period of 1 (one) year from the grant of the license, interruption for an equal period being permitted.

¶1. The patentee may request revocation of the license if the provisions of this article are not met.
¶2. The licensee will be vested with all powers to act in defense of the patent.
¶3. After grant of a compulsory license, the assignment thereof will only be permitted when effected together with the assignment, transfer or leasing of that part of the undertaking that exploits it.
Chapter IX. Patents of Interest to National Defense

Article 75. A patent application originated in Brazil the object of which is of interest to national defense will be processed in secrecy and will not be subject to the publications provided for in this statute.

¶1. The BRPTO will send the application immediately to the competent organ of the Executive Authorities for the purpose of providing, within 60 (sixty) days, an opinion regarding secrecy. After such period has passed without any opinion by the competent organ, the application will be processed normally.

¶2. Excepting express authorization by the competent organ, the filing abroad of a patent application the subject matter of which is considered to be of interest to national defense, as well as any disclosure thereof, is prohibited.

¶3. The exploitation and the assignment of an application or patent of interest to national defense are conditioned to prior authorization by the competent organ, due compensation being guaranteed whenever this implies a restriction to the rights of the applicant or patentee.

Chapter X. Certificate of Addition of an Invention

Article 76. On payment of a specific fee, the applicant or patentee of a patent of invention may request a certificate of addition to protect an improvement or development introduced in the subject matter of the invention, even if lacking inventive step, provided that it shares the same inventive concept.

¶1. If publication of the main application has already taken place, the application for the certificate of addition will be published immediately.

¶2. Substantive examination of the application for a certificate of addition will be in accordance with the provisions of articles 30 to 37, without prejudice to the provisions of the previous ¶.

¶3. An application for a certificate of addition will be rejected if its subject matter does not involve the same inventive concept.

¶4. The applicant may, within the period for appeal, by payment of the corresponding fee, request the conversion of an application for a certificate of addition into a patent application benefiting from the date of filing of the application for the certificate.

Article 77. A certificate of addition is accessory to the patent, has the same expiry date and accompanies it for all legal effects.

Sole ¶ In a nullity process, the patentee may request that the subject matter contained in the certificate of addition be examined to verify the possibility of its subsistence, without prejudice to the term of protection of the patent.

Chapter XI. Extinction of Patents

Article 78. A patent shall become extinct:

I. on expiry of the term of protection;
II. on waiver by the patentee, without prejudice to the rights of third parties;
III. on forfeiture;
IV. on non-payment of the annual fee, within the periods provided for in ¶2 of article 84 and in article 87; and
V. on non-observance of the provisions of article 217.

Sole ¶ Once a patent becomes extinct, its object falls within the public domain.

Article 79. Waiver will only be permitted if it does not prejudice the rights of third parties.
Article 80. A patent becomes forfeit, ex officio, or at the request of any party with a legitimate interest if, after 2 (two) years from the grant of the first compulsory license, such period has not been sufficient to prevent or correct abuse or disuse, excepting legitimate reasons.

¶1. A patent will become forfeit when, on the date of application for forfeiture or of the ex officio commencement of the respective process, its exploitation has not been initiated.

¶2. In the process for forfeiture commenced at the request of any party with a legitimate interest, the BRPTO may continue the process on waiver by that party.

Article 81. The patentee will be notified to respond to the forfeiture request within a period of 60 (sixty) days, the onus of proof regarding exploitation falling on him.

Article 82. A decision will be pronounced within 60 (sixty) days counted from the end of the period mentioned in the previous article.

Article 83. A decision of the forfeiture process will produce effect as from the day of the request or of the publication of the commencement of the ex officio process.

Chapter XII. Annual Fees

Article 84. The applicant and patentee are subject to the payment of annual fees, as from the beginning of the third year from the date of filing.

¶1. Advance payment of the annual fees will be regulated by the BRPTO.

¶2. The payment should be effected within the first 3 (three) months of each annual period, but may still be effected within the following 6 (six) months, independently of notification, by payment of an additional fee.

Article 85. The provisions of the previous article apply to international applications filed in virtue of a treaty in force in Brazil, the payment of annual fees due before the date of entry into national processing having to be effected within a period of 3 (three) months from that date.

Article 86. Failure to pay an annual fee, under the terms of articles 84 and 85, will result in the dismissal of the application or extinction of the patent.

Chapter XIII. Restoration

Article 87. A patent application and patent may be restored, if the applicant or patentee so requests, within 3 (three) months counted from notification of dismissal of the application or extinction of the patent, on payment of a specific fee.

Chapter XIV. Inventions and Utility Models Made by Employees or Suppliers of Services

Article 88. An invention or utility model will belong exclusively to the employer when it results from a work contract being executed in Brazil and the object of which is research or the exercise of inventive step or when such results from the nature of the services for which the employee was contracted.

¶1. Except when there are express contractual provisions to the contrary, remuneration for the work to which
this article refers will be limited to the salary agreed upon.

¶2. In the absence of proof to the contrary, an invention or utility model for which a patent is requested by an employee within 1 (one) year from the extinction of the contract of employment will be considered as having been developed while the contract was in force.

Article 89. An employer, who is the proprietor of a patent, may grant the employee, who is the author of the invention or improvement, participation in the economic gains resulting from the exploitation of the patent, as a result of negotiation with the interested party or as provided for by a norm of the undertaking.

Sole ¶ The participation referred to in this article will not in any way be incorporated into the salary of the employee.

Article 90. An invention or utility model developed by an employee will belong exclusively to the employee provided that it is unconnected to his work contract and when it does not result from the use of resources, means, data, materials, installations or equipment of the employer.

Article 91. The ownership of an invention or utility model will be common, in equal parts, when it results from the personal contribution of the employee and from resources, data, means, installations or equipment of the employer, without prejudice to express contractual provisions to the contrary.

¶1. When there is more than one employee, the part due to them will be divided equally between all of them, except when agreed to the contrary.

¶2. The employer will be guaranteed the right to an exclusive license for exploitation and the employee will be guaranteed fair remuneration.

¶3. Exploitation of the subject matter of the patent, in the absence of an agreement, must be initiated by the employer within 1 (one) year counted from the date of grant, under penalty of the property in the patent being transferred to the exclusive ownership of the employee, without prejudice to the hypothesis of lack of exploitation for legitimate reasons.

¶4. In the case of assignment, any of the co-owners may exercise the right of preference under identical conditions.

Article 92. The provisions of the preceding articles, as far as they are applicable, apply to the relationship between an autonomous worker or a trainee and the contracting undertaking and between contracting and contracted undertakings.

Article 93. The provisions of this Chapter, as far as they are applicable, apply to entities of the direct or indirect and foundational, federal, state or municipal, Public Administration.

Sole ¶ In the hypothesis of article 88, a reward corresponding to part of the value of the advantages obtained as a result of the application or the patent will be guaranteed to the inventor, under the terms and conditions provided for in the statutes or internal regulations of the entity to which this article refers.

II. INDUSTRIAL DESIGNS

CHAPTER I. OWNERSHIP

Article 94. The author is assured the right to obtain a registration of an industrial design that guarantees to him the property, under the terms established by this statute.

Sole ¶ As far as they are applicable, the provisions of articles 6 and 7 will apply to the registration of industrial designs.
CHAPTER II. REGISTRATION

§I. REGISTRABLE INDUSTRIAL DESIGNS

Article 95. An industrial design is considered any ornamental plastic form of an object or any ornamental arrangement of lines and colors that may be applied to a product, that provides a new and original visual result in its external configuration, and that may serve as a type for industrial manufacture.

Article 96. An industrial design is considered new when not comprised by the state of the art.

¶1. The state of the art comprises everything made accessible to the public before the date of filing of the application, in Brazil or abroad, by use or any other means, without prejudice to the provisions of ¶ 3 of this article and of article 99.

¶2. For the sole purpose of determining novelty, the whole contents of an application for a patent or a registration filed in Brazil, but not yet published, will be considered as included in the state of the art from the date of filing, or from the priority claimed, provided that it is published, even though subsequently.

¶3. An industrial design of which disclosure occurred within the 180 (one hundred and eighty) days preceding the date of filing the application or of the priority claimed will not be considered as included in the state of the art, provided such disclosure is made in accordance with the situations provided for in items I to III of article 12.

Article 97. An industrial design is considered original when it results in a distinctive visual configuration in relation to other prior objects.

Sole ¶ The original visual result may be the result of the combination of known elements.

Article 98. Works of a purely artistic nature are not considered to be industrial designs.

§II. PRIORITY

Article 99. As far as they are applicable, the provisions of article 16, except for the time limit provided for in ¶ 3 of that article, which will be 90 (ninety) days, apply to applications for registration.

§III. NON-REGISTRABLE INDUSTRIAL DESIGNS

Article 100. An industrial design is not registrable for:

I. when it is contrary to morals and good customs or which offends the honor or image of people or is contrary to the liberty of conscience, belief, religious cults or ideas and feelings worthy of respect and veneration.

II. the necessary common or ordinary shape of an object or, further, when is determined essentially by technical or functional considerations.

CHAPTER III. APPLICATIONS FOR REGISTRATION

§I. FILING OF THE APPLICATION

Article 101. An application for registration, in accordance with conditions established by the BRPTO, will contain:

I. a request;

II. a specification, if applicable;
III. claims, if applicable;
IV. drawings or photographs;
V. the field of application of the object; and
VI. proof of payment of the filing fee.

Sole ¶ The documents that comprise an application for registration must be filed in the Portuguese language.

Article 102. Once presented, the application will be submitted to a preliminary formalities review and, if in due order, will be protocolled, the filing date being considered to be the date of presentation.

Article 103. An application that does not formally meet the requirements of article 101, but which does contain sufficient data relating to the applicant, to the industrial design and to the author, may be delivered to the BRPTO against a dated receipt which will establish the requirements to be met within a period of 5 (five) days, under penalty of being considered nonexistent.

Sole ¶ Once the requirements have been met, filing will be considered to have been made on the date of presentation of the application.

§II. CONDITIONS OF THE APPLICATION

Article 104. An application for an industrial design registration must refer to a single object, a plurality of variations being permitted, provided that they are destined for the same purpose and maintain between them the same preponderant distinctive characteristic, each application being limited to a maximum of 20 (twenty) variations.

Sole ¶ The drawing must clearly and sufficiently represent the object and its variations, if they exist, so as to allow its reproduction by a person skilled in the art.

Article 105. When secrecy is requested under the terms of article 106, ¶1, the application may be withdrawn up to 90 (ninety) days counted from the date of filing.

Sole ¶ Withdrawal of an earlier application without producing any effect will confer priority on the first later application.

§III. PROSECUTION AND SUBSTANTIVE EXAMINATION OF AN APPLICATION

Article 106. Once an application for an industrial design registration has been filed and the provisions of articles 100, 101 and 104 have been observed, it will be published automatically and the registration will be simultaneously granted, the respective certificate being issued.

¶1. On request by the applicant at the time of filing, the application may be kept secret for a period of 180 (one hundred and eighty) days counted from the filing date, after which it will be processed.

¶2. If the applicant avails himself of the provisions of article 99, processing of the application will await presentation of the priority document.

¶3. If the provisions of articles 101 and 104 are not met, an office action will be made to which a response should be filed within 60 (sixty) days, under penalty of definitive dismissal.

¶4. If the provisions of article 100 are not met, the application for registration will be rejected.

CHAPTER IV. GRANT AND TERM OF THE REGISTRATION

Article 107. The certificate must include the number and title, the name of the author, observing the provisions of
¶4 of article 6, the name, nationality and domicile of the registrant, the term, the drawings, data relating to any foreign priority and, when applicable, the specification and claims.

**Article 108.** The registration will have a term of 10 (ten) years counted from the date of filing and will be renewable for three successive periods of 5 (five) years each.

¶1. An application for renewal must be made during the last year of the term of the registration and be accompanied by proof of payment of the respective fee.

¶2. If an application for renewal has not been requested prior to the end of the term of the registration, the registrant may make such request within the subsequent 180 (one hundred and eighty) days, on payment of an additional fee.

**Chapter V. Protection Conferred by a Registration**

**Article 109.** The property in an industrial design is acquired by a validly granted registration.

Sole ¶ As far as applicable, the provisions of article 42 and of items I, II and IV of article 43, will apply.

**Article 110.** A person who in good faith, prior to the date of filing or of the priority of an application for registration, exploited the subject matter in this country, will be guaranteed the right to continue the exploitation in the previous manner and conditions, without onus.

¶1. The right conferred under the terms of this article can only be ceded, by transfer or leasing, together with the business or undertaking, or part thereof that has direct relation with the exploitation of the object of the registration.

¶2. The right to which this article refers will not be guaranteed to a person who had knowledge of the object of the registration due to disclosure under the terms of ¶3 of article 96, provided that the application was filed within 6 (six) months from the disclosure.

**Chapter VI. Examination on Merit**

**Article 111.** A registrant of an industrial design may, at any time during the term of registration, request examination as to novelty and originality of the object of the registration.

Sole ¶ The BRPTO will issue an opinion on merit that will serve as the basis for the ex officio institution of nullity proceedings of the registration if it is concluded that at least one of the requirements provided for in articles 95 to 98 are absent.

**Chapter VII. Nullity of Registrations**

**§I. General Provisions**

**Article 112.** A registration is null if granted contrary to the provisions of this statute.

¶1. Nullity of a registration will produce effects as from the date of filing of the application.

¶2. In the case of inobservance of the provisions of article 94, the author may alternatively claim adjudication of the registration.

**§II. Administrative Nullity Proceedings**

**Article 113.** Nullity of a registration will be declared administratively when it has been granted contrary to articles 94 to 98.
§1. Nullity proceedings may be instituted ex officio or upon request of any person having a legitimate interest within 5 (five) years from grant of the registration, without prejudice to the hypothesis provided for in the sole ¶ of article 111.

¶2. A request or ex officio institution will suspend the effects of grant of a registration if presented or published within 60 (sixty) days from grant.

**Article 114.** The registrant will be notified to respond within 60 (sixty) days counted from the date of the publication.

**Article 115.** The BRPTO will issue an opinion after the period specified in the previous article, whether there is a response or not, notifying the registrant and the applicant to respond within 60 (sixty) days.

**Article 116.** After the period specified in the previous article, even if no responses have been made, the process will be decided by the Commissioner of the BRPTO, thereby bringing to a close the administrative sphere.

**Article 117.** Nullity proceedings will be continued even when the registration is extinct.

### §III. NULLITY ACTION

**Article 118.** As far as they are applicable, the provisions of articles 56 and 57 will apply to actions for nullity of a registration for an industrial design.

### CHAPTER VIII. EXTINCTION OF REGISTRATIONS

**Article 119.** A registration will become extinct:

I. on expiry of the term of protection;
II. on waiver by the registrant, without prejudice to the rights of third parties;
III. on non-payment of the fee, provided for in articles 108 and 120; or
IV. on non-observance of the provisions of article 217.

### CHAPTER IX. QUINQUENNIAL FEE

**Article 120.** The proprietor of a registration is subject to the payment of a quinquennial fee as of the second quinquennial from the filing date.

¶1. Payment of the second quinquennial will be made during the 5 (fifth) year of the term of the registration.

¶2. Payment of the following quinquennial fees will be presented together with the application for renewal referred to in article 108.

¶3. Payment of quinquennial fees may still be made within the 6 (six) months following the period established in the previous ¶, by payment of an additional fee.

### CHAPTER X. FINAL PROVISIONS

**Article 121.** As far as they are applicable, the provisions of articles 58 to 63 apply to subject matter covered by the present Title, the rights of the employee or supplier of services being governed by the provisions of articles 88 to 93.
III. MARKS

CHAPTER I. REGISTRATION

§I. SIGNS REGISTRABLE AS MARKS

Article 122. Any visually perceptive distinctive sign, when not prohibited under the law, is susceptible of registration as a mark.

Article 123. For the effects of this statute, the following definitions apply:

I. product or service mark: that used to distinguish a product or service from one having a different origin, that is identical, similar or akin;

II. certification mark: that used to attest that a product or service conforms with determined technical norms or specifications, notably with reference to its quality, its nature, the material used and the methodology employed; and

III. collective mark: that used to identify products or services originated by members of a given entity.

§II. SIGNS NOT REGISTRABLE AS MARKS

Article 124. The following are not registrable as marks:

I. crests, armorial bearings, medals, flags, emblems, official public distinctions and monuments, be they national, foreign or international, as well as any respective designations, figures or imitations;

II. an isolated letter, digit or date, except when sufficiently distinctive;

III. expressions, figures, drawings or any other sign contrary to morals and good customs or which offend a person’s honor or image or are an affront to the liberty of conscience, beliefs, religious cults or to ideas and sentiments worthy of respect and veneration;

IV. designations or acronyms of a public entity or establishment, when registration is not requested by that public entity or establishment;

V. reproductions or imitations of a characteristic or differentiating element of a title of establishment or the name of an undertaking belonging to a third party, which are likely to cause confusion or association with such distinctive signs;

VI. signs of a generic, necessary, common, usual or simply descriptive character, when related to the product or service to be distinguished, or those commonly used to designate a characteristic of the product or service with respect to its nature, nationality, weight, value, quality and moment of production or of giving a service, except when presented in a sufficiently distinctive manner;

VII. signs or expressions used only as a means of advertising;

VIII. colors and their names, except when arranged or combined in an unusual and distinctive manner;

IX. geographic indications, imitations thereof likely to cause confusion or signs that might falsely suggest a geographic indication;

X. signs that suggest a false indication with respect to origin, source, nature, quality or utility of the product or service to which the mark is directed;

XI. reproductions or imitations of official seals, normally adopted for the guarantee of a standard of any type or nature;

XII. reproductions or imitations of signs that have been registered as a collective or a certification mark by a third party, without prejudice to the provisions of article 154; XIII - names, prizes or symbols of sporting, artistic, cultural, social, political, economic or technical official or officially recognized events, as well as imitations likely to
cause confusion, except when authorized by the competent authority or entity promoting the event;
XIV. reproductions or imitations of titles, bonds, coins and bank notes of the Union, the States, the Federal District, the Territories, the Municipalities or of any country;
XV. personal names or signatures thereof, family or patronymic names and images of third parties, except with the consent of the owner, his heirs or his successors;
XVI. well-known pseudonyms or nicknames and singular or collective artistic names, except with the consent of the owner, his heirs or his successors;
XVII. literary, artistic or scientific works, as well as titles protected by copyright and likely to cause confusion or association, except with the consent of the author or owner;
XVIII. technical terms used in the industry, science or art that is related to the product or service to be distinguished;
XIX. reproductions or imitations, in whole or in part, even with additions, of a mark registered by a third party, to distinguish or certify a product or service that is identical, similar or akin, and which are likely to cause confusion or association with the third party's mark;
XX. duplications of marks of a single proprietor for the same product or service, except when, in the case of marks of the same nature, they are presented in a sufficiently distinctive manner;
XXI. necessary, common or usual shapes of a product or of its packaging, or, furthermore, shapes that cannot be disassociated from a technical effect;
XXII. objects that are protected by industrial design registrations in the name of third parties; and
XXIII. signs that imitate or reproduce, wholly or in part, a mark of which the applicant could obviously not fail to have knowledge in view of his activity, and of which the proprietor is established or domiciled in the national territory or in a country with which Brazil maintains an agreement or guarantees reciprocity of treatment, if the mark is intended to distinguish a product or service that is identical, similar or akin, and is likely to cause confusion or association with such third party mark.

§III. FAMOUS MARKS

Article 125. Marks registered in Brazil and considered to be famous will be guaranteed special protection, in all fields of activity.

§IV. WELL-KNOWN MARKS

Article 126. Marks that are well-known in their field of activity in the terms of article 6 bis (1) of the Paris Convention for the Protection of Industrial Property will enjoy special protection, independently of whether they have been previously filed or registered in Brazil.

¶1. The protection to which this article refers is also applicable to service marks.

¶2. The BRPTO may reject ex officio an application to register a mark that wholly or partially reproduces or imitates a well-known mark.

CHAPTER II. PRIORITY

Article 127. Priority rights will be guaranteed to an application for the registration of a mark filed in a country that maintains an agreement with Brazil or in an international organization, that produces the effect of a national filing, within the time limits established in the agreement, the filing not being invalidated nor prejudiced by facts that occur within such time limits.

¶1. The priority claim must be made at the time of filing, but may be supplemented within 60 (sixty) days by
Chapter III. Applicants for Registration

Article 128. Private individuals or private or public legal entities may apply for the registration of a mark.

§1. Private legal entities may only request the registration of a mark relating to the activity that they effectively and licitly exercise directly or through undertakings that they control directly or indirectly, and such condition should be stated on the actual request, subject to the penalties of the law.

§2. The registration of a collective mark may only be requested by a legal entity representing a group and able to exercise an activity different from that of its members.

§3. The registration of a certification mark can only be requested by a person without any direct commercial or industrial interest in the product or service being certified.

§4. A priority claim does not exempt the application from the provisions of this Title.

Chapter IV. Rights Relating to a Mark

§I. Acquisition

Article 129. The property in a mark is acquired by a validly issued registration, in accordance with the provisions of this statute, the owner being guaranteed exclusive use thereof throughout the national territory, without prejudice to the provisions of articles 147 and 148 with respect to collective and certification marks.

§1. Any person who in good faith at the date of priority or of the application was using an identical or similar mark for at least 6 (six) months in the country, to distinguish or certify a product or service that is identical, similar or akin, will have preferential right to registration.

§2. The preferential right can only be ceded, by transfer or leasing, together with the business of an undertaking, or part thereof, that has a direct relation to the use of the mark.

§II. Protection Afforded by a Registration

Article 130. The registrant of, or applicant for, a mark is also guaranteed the right to:

I. assign his registration or application for registration;

II. license its use;

III. care for its material integrity or reputation.

Article 131. The protection afforded by this statute extends to the use of the mark on papers, printed matter, advertisements and documents related to the activity of the owner.

Article 132. The owner of a mark may not:
I. prevent tradesmen or distributors from using distinctive signs that belong to them, together with the mark of the product for its promotion and commercialization;
II. prevent manufacturers of accessories;
III. prevent the free circulation of products placed on the internal market by himself or by another with his consent, without prejudice to the provisions of ¶3 and ¶4 of article 68; and
IV. prevent the mention of the mark in speeches, scientific or literary works or in any other type of publication, if it is made without any commercial connotation and without prejudice to its distinctive character.

CHAPTER V. TERM, ASSIGNMENT AND NOTATIONS

§I. TERM

Article 133. The registration of a mark will have a term of 10 (ten) years counted from the date of its grant, it being renewable for equal and successive periods.
¶1. An application for renewal must be made during the last year of the term of the registration and must be accompanied by proof of payment of the respective fee.
¶2. If the request for renewal has not been made by the end of the registration, the proprietor may make such request within the following 6 (six) months on payment of an additional fee.
¶3. Renewal will not be granted if the provisions of article 128 are not met.

§II. ASSIGNMENT

Article 134. Applications for registration and registrations may be assigned, provided that the assignee meets the legal requirements for requesting such registration.

Article 135. An assignment must include all the registrations or applications, in the name of the assignee, for identical or similar marks relating to a product or service that is identical, similar or akin, under penalty of cancellation of the registrations or dismissal of the unassigned applications.

§III. NOTATIONS

Article 136. The BRPTO will make a note of the following:
I. assignments, indicating the complete qualification of the assignee;
II. any limitation or onus on the application or registration; and
III. alterations of the name, headquarters or address of the applicant or registrant.

Article 137. Notations will produce effect with respect to third parties as from the date of their publication.

Article 138. Appeals may be filed against a decision which:
I. rejects the notation of assignment; and
II. cancels the registration or dismisses the application under the terms of article 135.

§IV. LICENSE OF USE

Article 139. The proprietor of a registration or the applicant of an application for registration may enter into
a license contract for use of the mark, without prejudice to his right to exercise effective control over the specifications, nature and quality of the respective products or services.

**Sole ¶** The licensee may be vested by the registrant with full powers to act in defense of the mark, without prejudice to his own rights.

**Article 140.** License contracts must be registered at the BRPTO in order to produce effect with respect to third parties.

¶1. Registrations will produce effect with respect to third parties as from the date of their publication.

¶2. In order to validate proof of use, license contracts need not be registered at the BRPTO.

**Article 141.** An appeal may be filed against a decision rejecting the registration of a license agreement.

**CHAPTER VI. LOSS OF RIGHTS**

**Article 142.** The registration of a mark will become extinct:

I. on expiry of the term of protection;
II. on waiver, which may be total or partial with respect to the products or services indicated by the mark;
III. by forfeiture; or
IV. for failure to observe the provisions of article 217.

**Article 143.** A registration will become forfeit, on the request of any person with a legitimate interest, if, after 5 (five) years from its grant, on the date of such request:

I. use of the mark in Brazil has not been initiated; or
II. use of the mark has been interrupted for more than 5 (five) consecutive years or if, within that time, the mark has been used in a modified form that implies alteration in its original distinctive character, as found on the certificate of registration.

¶1. The mark will not become forfeit if the registrant justifies the lack of use for legitimate reasons.

¶2. The registrant will be notified to reply within a period of 60 (sixty) days, the onus falling on him to prove the use of the mark or justify its lack of use for legitimate reasons.

**Article 144.** Use of the mark must include products or services mentioned on the certificate, under penalty of partial forfeiture of the registration with respect to those products or services not similar or akin to those for which use of the mark has been proved.

**Article 145.** No recognition will be given to requests for forfeiture if use of the mark has been proved or if its lack of use has been justified in an earlier procedure requested less than 5 (five) years previously.

**Article 146.** An appeal may be filed against a decision which either declares or rejects forfeiture.

**CHAPTER VII. COLLECTIVE AND CERTIFICATION MARKS**

**Article 147.** An application for the registration of a collective mark must include regulations of use, determining the conditions and prohibitions for use of the mark.

**Sole ¶** The regulations of use, when they do not accompany the application, must be protocolled within a period of 60 (sixty) days from filing, under penalty of definitive dismissal of the application.
**Article 148.** An application for the registration of a certification mark must include:

I. the characteristics of the product or the service to be certified; and
II. the measures of control that are to be adopted by the registrant.

Sole ¶ The documentation foreseen in items I and II of this article, when not accompanying the application, must be protocolled within a period of 60 (sixty) days, under penalty of definitive dismissal of the application.

**Article 149.** Any alteration in the regulations of use must be communicated to the BRPTO, by means of a duly protocolled petition, containing all the altered conditions, under penalty of it not being considered.

**Article 150.** Use of the mark will be independent of a license, it being sufficient for its authorization to be contained in the regulations of use.

**Article 151.** Apart from the grounds for extinction established in article 142, registrations for collective and certification marks will become extinct when:

I. the entity ceases to exist; or
II. the mark is used under conditions that differ from those foreseen in the regulations of use.

**Article 152.** Waiver of a registration for a collective mark will only be admitted when requested in accordance with the terms of the articles of association or statutes of the entity itself or, further, in accordance with the regulations of use.

**Article 153.** Forfeiture of the registration will be declared if the collective mark is not used by more than one authorized person, without prejudice to the provisions of articles 143 to 146.

**Article 154.** Collective marks and certification marks that have already been used and the registrations of which have become extinct may not be registered in the name of a third party, prior to the expiry of a period of 5 (five) years counted from the extinction of the registration.

**Chapter VIII. Filing**

**Article 155.** The application must refer to a single distinctive sign and, in accordance with the conditions established by the BRPTO, must contain:

I. a request;
II. prints, when applicable; and
III. proof of payment of the filing fee.

Sole ¶ the request and any documents that accompany it must be presented in the Portuguese language and, whenever there is a document in a foreign language, a simple translation must be presented at the time of filing the application or within the following 60 (sixty) days, under penalty of the document not being taken into consideration.

**Article 156.** Once the application has been filed, it will be submitted to a preliminary formalities review and, if in due order, will be protocolled, the filing date being considered as the date of its presentation.

**Article 157.** Applications that do not formally meet the provisions of article 155, but which contain sufficient data relating to the applicant, the sign of the mark and the class, may be delivered to the BRPTO, against a dated receipt which will establish the requirements to be met by the applicant within 5 (five) days, under penalty of being considered non-existent.
Once the requirements have been met, the filing will be considered as having been made on the date of presentation of the application.

CHAPTER IX. EXAMINATION

Article 158. Once protocolled, the application will be published for the filing of oppositions within a period of 60 (sixty) days.

1. The applicant will be notified of the opposition and may respond within a period of 60 (sixty) days.
2. Oppositions, administrative nullity procedures and nullity actions based on item XXIII of article 124, or article 126 will not be recognized if proof of the filing of an application for the registration of the mark in accordance with this statute is not provided within 60 (sixty) days after filing the opposition or nullity procedure or action.

Article 159. Once the period for opposition has passed or, if such has been filed, after the period for reply, examination will be conducted during which office actions may be formulated, which must be responded to within a period of 60 (sixty) days.

1. If no response to an office action is filed, the application will be definitively dismissed.
2. Once a response has been filed, even if the requirement has not been met or the formulation thereof has been reconsidered, examination will be continued.

Article 160. Once examination has been concluded, a decision will be issued, allowing or rejecting the application for registration.

CHAPTER X. ISSUANCE OF CERTIFICATES OF REGISTRATIONS

Article 161. A certificate of registration will be granted after the application has been allowed and payment of the corresponding fees has been proved.

Article 162. The payment of the fees and the respective proof thereof, relating to the issuance of the certificate of registration and the first ten year period of protection, must be effected within 60 (sixty) days counted from allowance.

Sole ¶ The fees may still be paid and proved within 30 (thirty) days after the period mentioned in this article, independently of notification, by payment of a specific fee, under penalty of definitive dismissal of the application.

Article 163. The certificate of registration will be considered to have been granted on the date of publication of the corresponding act.

Article 164. The certificate will mention the mark, the number and date of the registration, the name, nationality and domicile of the registrant, the products or services, the characteristics of the registration and the foreign priority.

CHAPTER XI. NULLITY OF REGISTRATIONS

§1. GENERAL PROVISIONS

Article 165. A registration is null if granted contrary to the provisions of this statute.
Sole ¶ Nullity of a registration may be total or partial, it being a condition for partial nullity that the remaining part can be considered registrable.
**Article 166.** The proprietor of a mark registered in a country that is signatory to the Paris Convention for the Protection of Industrial Property may, alternatively, by means of a court action, claim adjudication of the registration, in accordance with the terms of article 6f (1) of the Convention.

**Article 167.** A declaration of nullity will produce effect as from the date of filing of the application.

### §II. Administrative Nullity Procedure

**Article 168.** Nullity of a registration may be declared administratively if it was granted in conflict with the provisions of this statute.

**Article 169.** A nullity procedure may be commenced ex officio or on the request of any person with a legitimate interest, within 180 (one hundred and eighty) days counted from the date of issuance of the certificate of registration.

**Article 170.** The registrant will be notified to respond within a period of 60 (sixty) days.

**Article 171.** Once the period referred to in the previous article has passed and even if no response has been presented, the procedure will be decided by the Commissioner of the BRPTO, thereby terminating the administrative sphere.

**Article 172.** The nullity proceedings will be continued even if the registration is extinct.

### §III. Nullity Actions

**Article 173.** A nullity action may be filed by the BRPTO or by any person with a legitimate interest.  
**Sole ¶** The judge may, in the course of the proceedings, grant an injunction suspending the effects of the registration and of the use of the mark, provided the appropriate procedural requirements are met.

**Article 174.** The limitation for bringing an action for declaring the nullity of a registration is 5 (five) years from the date of registration.

**Article 175.** Nullity actions must be brought before the Federal Courts of Justice and the BRPTO, when it is not the plaintiff, will participate in the action.  
¶1. The period for reply by a defendant that is a registrant will be 60 (sixty) days.  
¶2. Once the decision in a nullity action is res judicata, the BRPTO will publish a note for the notification of third parties.

### IV. Geographical Indications

**Article 176.** A geographical indication is constituted by an indication of source or an appellation of origin.

**Article 177.** An indication of source is considered to be the geographical name of a country, city, region or locality of its territory, which has become known as a center of extraction, production or manufacture of a determined product or for providing a determined service.
Article 178. An appellation of origin is considered to be the geographical name of a country, city, region or locality of its territory, which designates a product or service, the qualities or characteristics of which are exclusively or essentially due to the geographical environment, including natural and human factors.

Article 179. Protection is extended to the graphical or figurative representation of a geographical indication, as well as to the geographical representation of the country, city, region or locality of its territory of which the name is a geographical indication.

Article 180. When a geographical name comes into common use, with respect to a given product or service, it will not be considered as a geographical indication.

Article 181. A geographical name that does not constitute an indication of source or an appellation of origin may serve as a characteristic element of a product or service mark, if it does not suggest a false source.

Article 182. The use of a geographical indication is restricted to the producers and providers of services established in the locality, quality requirements also having to be met in relation to appellations of origin. The BRPTO will establish the conditions of registration for geographical indications.

V. CRIMES AGAINST INDUSTRIAL PROPERTY

CHAPTER I. CRIMES AGAINST PATENTS

Article 183. A crime is committed against a patent of invention or a utility model patent by he who:
   I. manufactures a product that is the subject matter of a patent of invention or a utility model patent, without authorization of the patentee; or
   II. uses a means or process that is the subject matter of a patent of invention, without authorization of the patentee.
Penalty. detention of 3 (three) months to 1 (one) year, or a fine.

Article 184. A crime is committed against a patent of invention or a utility model patent by he who:
   I. exports, sells, exhibits or offers for sale, maintains in stock, hides or receives, with a view to use for economic purposes, a product manufactured in violation of a patent of invention or of a utility model patent, or that is obtained by a patented means or process; or
   II. imports a product that is the subject matter of a patent of invention or of a utility model patent or is obtained by a means or process patented in this country, for the purposes mentioned in the previous item, and that has not been placed on the external market directly by the proprietor or with his consent.
Penalty - detention of 1 (one) to 3 (three) months, or a fine.

Article 185. Supplying a component of a patented product, or material or equipment for carrying out a patented process, provided that the final application of the component, material or equipment necessarily leads to the exploitation of the subject matter of the patent. Penalty - detention of 1 (one) to 3 (three) months or a fine.

Article 186. The crimes of this Chapter are committed even if the violation does not affect all the claims of the patent or if it is restricted to the use of means equivalent to the subject matter of the patent.
CHAPTER II. CRIMES AGAINST INDUSTRIAL DESIGNS

Article 187. Manufacturing, without the authorization of the registrant, a product that incorporates a registered industrial design, or a substantial imitation thereof that may lead to error or confusion.
Penalty. detention of 3 (three) months to 1 (one) year, or a fine.

Article 188. A crime is committed against an industrial design registration by he who:
I. exports, sells, exhibits or offers for sale, maintains in stock, hides or receives, with a view to use for economic purposes, an object that illicitly incorporates a registered industrial design, or a substantial imitation thereof that may lead to error or confusion; or
II. imports a product that incorporates an industrial design registered in this country, or a substantial imitation thereof that may lead to error or confusion, for the purposes provided for in the previous item, and which was not placed on the external market directly by the registrant or with his consent.
Penalty. detention of 1 (one) to 3 (three) months, or a fine.

CHAPTER III. CRIMES AGAINST MARKS

Article 189. A crime is committed against the registration of a mark by he who:
I. reproduces a registered mark wholly or in part, without the authorization of the registrant, or imitates it in a manner that may induce confusion; or
II. alters the registered mark of a third party already applied to a product placed on the market.
Penalty. detention of 3 (three) months to 1 (one) year, or a fine.

Article 190. A crime is committed against the registration of a mark by he who imports, exports, sells, offers or exhibits for sale, hides or maintains in stock:
I. a product branded with an illicitly, wholly or partially, reproduced or imitated mark of a third party; or
II. a product from his industry or commerce, held in a vessel, container or package carrying a legitimate mark of a third party.
Penalty. detention of 1 (one) to 3 (three) months, or a fine.

CHAPTER IV. CRIMES COMMITTED BY MEANS OF MARKS, TITLES OF ESTABLISHMENT AND ADVERTISING SIGNS

Article 191. Reproducing or imitating wholly or in part, in a manner that may lead to error or confusion, armorial bearings, crests or official public distinctions, be they national, foreign or international, without the necessary authorization, in a mark, title of establishment, commercial name, insignia or advertising sign, or using such reproductions or imitations for economic purposes.
Penalty. detention of 1 (one) to 3 (three) months, or a fine.
Sole ¶ He who sells or exhibits or offers for sale products branded with such marks are subject to the same penalty.

CHAPTER V. CRIMES AGAINST GEOGRAPHICAL AND OTHER INDICATIONS

Article 192. Manufacturing, importing, exporting, selling, exhibiting or offering for sale or maintaining in stock a product that presents a false geographical indication. Penalty - detention of 1 (one) to 3 (three) months, or a fine.

Article 193. Using, on a product, container, casing, belt, label, invoice, circular, poster or on any other means of
disclosure or advertisement, indicative terms, such as “type”, “species”, “kind”, “system”, “similar”, “substitute”, “identical”, or the equivalent, without making clear the true source of the product.

**Penalty.** detention of 1 (one) to 3 (three) months, or a fine.

Article 194. Using a mark, commercial name, title of establishment, insignia, advertising expression or sign or any other form that indicates a source other than the true one, or selling or exhibiting for sale a product carrying such signs.

**Penalty.** detention of 1 (one) to 3 (three) months, or a fine.

**Chapter VI. Crimes of Unfair Competition**

Article 195. A crime of unfair competition is committed by he who:

I. publishes, by any means, a false affirmation, in detriment to a competitor, with a view to obtaining advantage;

II. provides or divulges, with respect to a competitor, false information, with a view to obtaining advantage;

III. uses fraudulent means to divert, for his own or a third party’s benefit, another’s clientele;

IV. uses another’s advertising expression or sign, or imitates it, in a manner to cause confusion between the products or establishments;

V. unduly uses another’s commercial name, title of establishment or insignia or sells, exhibits or offers for sale or maintains in stock a product with such references;

VI. substitutes, with his own name or company name, on a product of another party, the name or company name of such other party, without his consent.

VII. claims, as a means of advertising, to have received a prize or distinction that he did not obtain;

VIII. sells, exhibits or offers for sale, in another’s container or package, an adulterated or falsified product, or uses it to do business with a product of the same type, even if not adulterated or falsified, if the fact does not constitute a more serious crime;

IX. gives or promises money or other utility to the employee of a competitor, whereby that employee, in failing in his duty in his employment, provides him with an advantage;

X. receives money or other utility, or accepts a promise of payment or reward, for, in failing in his duty in his employment, providing a competitor with an advantage;

XI - discloses, exploits or uses, without authorization, confidential knowledge, information or data, usable in industry, commerce or the providing of services, excepting that which is of public knowledge or which is obvious to a person skilled in the art, to which he has had access by means of a contractual or employment relationship, even after the termination of the contract;

XII. discloses, exploits or uses, without authorization, knowledge or information as mentioned in the previous item, when obtained directly or indirectly by illicit means or to which he has had access by fraud;

XIII. sells, exhibits or offers for sale a product which he declares to be subject of a patent filed or granted or of a registered industrial design, when it is not, or mention it, in a commercial announcement or paper, as filed or patented or registered, when it is not; or

XIV. divulges, exploits or uses, without authorization, the results of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products.

**Penalty.** detention of 3 (three) months to 1 (one) year, or a fine.

¶1. the employer, partner or administrator of an undertaking that commits an act falling within the types of crime established in items XI and XII of this article are included in the hypotheses to which such items refer.
\[2.\] The provisions of item XIV do not apply with respect to disclosure by a government entity competent to authorize commercialization of a product, when necessary to protect the public.

**Chapter VII. General Provisions**

**Article 196.** The penalties of detention provided for in Chapters I, II and III of this Title will be increased by one third to one half when:

I. the party is or was a representative, proxy, agent, partner or employee of the patentee or registrant or, further, of his licensee; or

II. the altered, reproduced or imitated mark is famous, is well-known or is a certification or collective mark.

**Article 197.** The penalties of fines provided for in this Title will be fixed at a minimum of 10 (ten) and a maximum of 360 (three hundred and sixty) days of fine, in accordance with the Criminal Code system.

**Sole ¶** The fine may be increased or reduced by up to 10 (ten) times in view of the personal conditions of the agent and of the magnitude of the advantage obtained, independently of the provisions established in the previous article.

**Article 198.** The customs authorities, ex officio or at the request of an interested party, may seize, at the time of checking, any products carrying falsified, altered or imitated marks or a false indication of source.

**Article 199.** An action against crimes provided for in this Title will be brought through the filing of a complaint, except in the case of the crime of article 191, in which case the criminal action will be public.

**Article 200.** Criminal actions and preliminary measures of search and seizure, in the case of crimes against industrial property, will be regulated by the provisions of the Criminal Process Code, with the modifications present in the articles of this Chapter.

**Article 201.** During execution of a search and seizure measure, with respect to a crime against a patent relating to a process, the bailiff will be accompanied by an expert who will verify, preliminarily, the existence of the illicit act, the judge being able to order the seizure of products obtained by the infringer using the patented process.

**Article 202.** Apart from the preliminary measures of search and seizure, the interested party may request:

I. seizure of a falsified, altered or imitated mark at its place of preparation or where it is found, prior to use for criminal purposes; or

II. destruction of a falsified mark on packets or products that contain it, before they are distributed, even if the packages or even the products themselves are destroyed.

**Article 203.** In the case of legally organized and publicly functioning industrial or commercial establishments, the preliminary measures will be limited to the inspection and seizure of the products, when so ordered by the judge, it not being permitted to paralyze their legally exercised activity.

**Article 204.** Once a search and seizure measure has been carried out, he who requested it in bad faith, in a spirit of rivalry, mere caprice or gross error will be liable for losses and damages.

**Article 205.** An allegation of nullity of the patent or registration on which the action is based may constitute
matter of defense in a criminal action. Absolution of the defendant, however, will not signify nullity of the patent or registration which can only be requested in an action before the competent courts.

**Article 206.** If, in the course of a court action, information is revealed that is of a confidential nature, be it an industrial or a trade secret, the judge must determine that the action continues “in camera”, the use of such information by the other party for other purposes also being forbidden.

**Article 207.** Independently of the criminal action, the aggrieved party may file civil actions that he considers suitable, as laid down in the Civil Process Code.

**Article 208.** Compensation will be determined by the benefits that the injured party would have gained had the violation not occurred.

**Article 209.** The aggrieved party is reserved the right to receive losses and damages in compensation for losses caused by acts of violation of industrial property rights and acts of unfair competition that are not provided for in this statute but which tend to prejudice another’s reputation or business or to cause confusion between commercial or industrial establishments or providers of services, or between products and services placed on the market.

¶1. The judge may, in the formal record of the same action, so as to avoid irreparable damages or damages that would be difficult to recover, grant an injunctive order to suspend the violation or act that has such in view, before summoning the defendant, against, if he judges necessary, monetary caution or a fiduciary guarantee.

¶2. In the case of flagrant reproduction or imitation of a registered mark, the judge may determine the seizure of all the merchandise, products, objects, packages, labels and others that carry the falsified or imitated mark.

**Article 210.** Loss of profits will be determined by the most favorable to the injured party of the following criteria.

I. The benefits that would have been gained by the injured party if the violation had not occurred;

II. The benefits gained by the author of the violation of the rights; or

III. The remuneration that the author of the violation would have paid to the proprietor of the violated rights for a granted license which would have legally permitted him to exploit the subject of the rights.

**VI. Transfer of Technology and Franchising**

**Article 211.** The BRPTO will effect the registration of contracts that involve transfer of technology, franchising contracts and the like so that they may produce effect with respect to third parties.

Sole ¶ A decision with respect to applications for the registration of contracts of the type to which this article refers will be given within a period of 30 (thirty) days counted from the date of the application for registration.

**VII. General Provisions**

**Chapter I. Appeals**

**Article 212.** In the absence of express provisions to the contrary, appeals may be filed against decisions provided for in this statute, within a period of 60 (sixty) days.

¶1. Appeals will be received with suspensive and full staying effects, all provisions pertinent to examination in the first instance, in so far as they are applicable, being applied.

¶2. An appeal cannot be filed against a decision which determines the definitive dismissal of an application
for a patent or for a design registration or against that which allows an application for a patent, a certificate of addition or the registration of a mark.

¶3. The appeals will be decided by the Commissioner of the BRPTO, thus ending the administrative sphere.

**Article 213.** Interested parties will be notified to file counter-arguments to the appeal, within a period of 60 (sixty) days.

**Article 214.** For the purposes of complementing the arguments of the appeal brief, the BRPTO can issue an office action, which should be met within the period of 60 (sixty) days.

**Sole ¶** Once the period defined in the “main section” has passed, a decision on the appeal will be given.

**Article 215.** An appeal decision is final with no right to appeal in the administrative sphere.

**Chapter II. Acts of the Parties**

**Article 216.** The acts provided for in this statute will be practiced by the parties or by their attorneys who should be duly qualified.

¶1. Powers of attorney, in the form of an original, an official copy or an authenticated photocopy, must be in the Portuguese language, consular legalization and notarial recognition being waived.

¶2. The power of attorney must be filed within 60 (sixty) days counted from the practice of the first act by the party in the process, independently of notification or office action, under penalty of dismissal, being definitive the dismissal of a patent application, an application for registration of an industrial design or an application for the registration of a mark being definitive.

**Article 217.** A person domiciled abroad must maintain permanently a duly qualified attorney resident in the country, with powers to represent him administratively and judicially, including for receiving summons.

**Article 218.** Petitions will not be recognized:

I. when presented after the legal deadline; or

II. when they are not accompanied by proof of payment of the respective fee having the value in force at the date of their presentation.

**Article 219.** Petitions, oppositions and appeals shall not be recognized when:

I. presented after the period provided for in this statute;

II. not having legal basis; or

III. not accompanied by proof of payment of the respective fee.

**Article 220.** The BRPTO will make use of the acts of the parties, whenever possible, making any applicable office actions.

**Chapter III. The Terms**

**Article 221.** The time limits established in this statute are continuous, the right to carry out the act becoming automatically extinct on their termination, unless the party proves that it was not carried out for legitimate reasons.

¶1. A legitimate reason is considered as an unforeseen event, outside the control of the party and which prevented the party from carrying out the act.

¶2. When legitimate reasons are recognized, the party will carry out the act within the period granted by the BRPTO.
Article 222. In calculating time limits, the first day should be excluded and the last day included.

Article 223. Time limits only begin to run from the first working day after notification which will be made by publication in the official means of communication of the BRPTO.

Article 224. In the absence of express stipulation in this statute, time limits for practicing acts will be 60 (sixty) days.

Chapter IV. Limitations

Article 225. The limitation for actions for repairing damages caused to industrial property rights is 5 (five) years.

Chapter V. Acts of the BRPTO

Article 226. Acts of the BRPTO in administrative processes relating to industrial property will only produce effect as from their publication in the respective official means of communication, except:
   I. those that expressly do not depend on notification or publication by virtue of the provisions of this statute;
   II. administrative decisions when notification is made by post or knowledge is given to the party interested in the process; and
   III. internal opinions and dispatches that do not need to be known by the parties.

Chapter VI. Classifications

Article 227. Classifications relative to the subject matter of Titles I, II and III of this statute will be established by the BRPTO, when they are not determined in an international treaty or agreement in force in Brazil.

Chapter VII. Fees

Article 228. Fees will be charged for the services provided for in this statute, the values and manner of collection of which will be established by act of the head officer of the federal public administrative entity to which the BRPTO is bound.

Chapter VIII. Transitory and Final Provisions

Article 229. The provisions of this Statute shall be applied to all pending applications, except with respect to the patentability of applications filed until December 31, 1994, where the object for which there is being sought protection comprises substances, matter or products obtained by chemical means or processes and alimentary and chemical-pharmaceutical substances, matter, mixtures or products and medicaments of any type, as well as the respective processes of obtaining or modifying them, and where the applicants have not used the right provided in Articles 230 and 231 of this Statute, and in which case those applications shall be considered as rejected for all purposes, the BPTO (Brazilian Patent and Trademark Office) being due to publish the notices concerning the cited rejections.

Sole ¶ The criteria for patentability established in this statute shall be applied to the applications relative to pharmaceutical products and chemical products intended for agriculture, having been filed between January 1, 1995 and May 14, 1997, from the effective date of filing of the application in Brazil or of the priority, where applicable, the protection being assured from the date the patent is granted, through the remaining term counted from the filing date in Brazil, limited to the term provided in the main section of article 40.
Article 229-A. The patent applications relative to processes filed between January 1, 1995 and May 14, 1997, and where to no protection was provided by Article 9, Subparagraph “c” of Statute #5,772 of December 21, 1971, shall be deemed rejected and the BPTO (Brazilian Patent and Trademark Office) shall be due to provide the publication of the notices concerning the cited rejection decisions.

Article 229-B. The patent applications relative to products filed between January 1, 1995 and May 14, 1997, to which no protection was granted in article 9, Subparagraph “c” of Statute No. 5,772 of December 21, 1971, and in connection therewith the filing applicants failed to avail themselves of the right provided in articles 230 and 231, shall be decided until December 31, 2004, pursuant to this Statute.

Article 229-C. The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior approval from the Brazilian FDA (ANVISA, in the Portuguese abbreviation).

Article 230. A patent application may be filed relating to substances, matter or products obtained by chemical means or processes and alimentary and chemical-pharmaceutical substances, matter, mixtures or products and medicaments of any type, as well as the respective processes of obtaining or modifying them, by he who has protection guaranteed by treaty or convention in force in Brazil, the date of the first foreign filing being recognized, provided that its subject matter has not been placed on any market on the direct initiative of the proprietor or by third parties with his consent, nor have third parties carried out, in this country, serious and effective preparations for exploiting the subject matter of the application or patent.

¶1. The application must be filed within the period of 1 (one) year from the publication of this statute and must indicate the date of the first application filed abroad.

¶2. Patent applications filed on the basis of this article will be published automatically, interested parties having the right to intervene, within a period of 90 (ninety) days, with respect to whether the conditions of the “main section” of this article have been met.

¶3. Without prejudice to articles 10 and 18 of this statute, and once the conditions established in this article have been met and grant of a patent in the country where the first application was filed has been proved, the patent will be granted in Brazil, exactly as granted in the country of origin.

¶4. A patent granted on the basis of this article will be guaranteed the remainder of the term of protection in the country where the first application was filed, counted from the date of filing in Brazil and limited to the term defined in article 40, the provisions of the sole ¶ thereof not being applicable.

¶5. An applicant that has a pending application, relating to substances, matter or products obtained by chemical means or processes and alimentary and chemical-pharmaceutical substances, matter, mixtures or products and medicaments of any type, as well as the respective processes of obtaining or modifying them, may file a new application, within the time period and under the conditions established in this article, submitting proof of desistance of the pending application.

¶6. The provisions of this statute will apply, where applicable, to applications filed and to patents granted in accordance with this article.

Article 231. A patent application may be filed relating to the matter to which the previous article refers by a national or a person domiciled in the country, the date of disclosure of the invention being guaranteed, provided that its subject matter has not been placed on any market on the direct initiative of the owner or by third parties with his consent, nor have third parties carried out, in this country, serious and effective preparations for exploiting the subject matter of the application.

¶1. The application must be filed within the period of 1 (one) year from the publication of this statute.
2. Patent applications filed on the basis of this article will be processed in accordance with the terms of this statute.

3. A patent granted on the basis of this article will be guaranteed the remainder of the term of protection of 20 (twenty) years from the date of disclosure of the invention, counted from the date of filing in Brazil.

4. An applicant that has a pending application, relating to the matter to which the previous article refers, may file a new application, within the time period and under the conditions established in this article, submitting proof of desistance of the pending application.

Article 232. The production or use, under the terms of the previous legislation, of substances, matter or products obtained by chemical means or processes and alimentary and chemical-pharmaceutical substances, matter, mixtures or products and medicaments of any type, as well as the respective processes of obtaining or modifying them, even when protected by product or process patents in another country, in accordance with a treaty or convention in force in Brazil, may continue under the same conditions existing prior to the approval of this statute.

1. No retroactive or future claim, of any value or on any grounds, will be admitted relating to products produced or processes used in Brazil in conformity with this article.

2. Likewise, no claim in the terms of the previous ¶ will be admitted when, during the period prior to the entry into force of this statute, significant investments have been made for the exploitation of a product or of a process as referred to in this article, even if they are protected by product or process patents in another country.

Article 233. Applications for the registration of advertising expressions and signs and for declarations of notoriety will be definitively dismissed whereas such registrations and declarations will remain in force for the remainder of their terms but may not be renewed.

Article 234. Guarantees of priority, as provided for in article 7 of Statute #5,772 of 21 December 1971, are guaranteed to the applicant until the end of any current time limit.

Article 235. All current time limits granted under Statute #5,772 of 21 December 1971 are guaranteed.

Article 236. Applications for industrial model and industrial design patents that were filed when Statute #5,772 of 21 December 1971 was in force, will automatically be named as applications for the registration of an industrial design and, for all legal effects, publication will be considered as already having been effected.

Sole ¶ In such adapted applications, payments will be considered for the effect of calculation of the quinquennial fee.

Article 237. The provisions of article 111 will not apply to applications for industrial model or industrial design patents that have already been examined in accordance with Statute #5,772 of December 21, 1971.

Article 238. Appeals filed when Statute #5,772 of December 21, 1971 was in force, will be decided in accordance therewith.

Article 239. The Government is authorized to promote any changes in the BRPTO that are necessary to ensure financial and administrative autonomy thereto, and the BRPTO is able to:

I. contract technical and administrative personnel by way of public competition;
II. establish a table of salaries for its employees, which will be subject to approval by the ministry to which the BRPTO is bound; and
III. propose a basic structure and internal regulations that will be subject to approval by the ministry to which the BRPTO is bound.
Expenses resulting from the application of this article will be at the cost of the funds of the BRPTO itself.

**Article 240.** Article 2 of Statute #5,648 of 11th December 1970 will be altered to have the following wording:

“Article 2 - The principal purpose of the BRPTO is the execution, nationally, of the norms that regulate industrial property, taking into account its social, economic, juridical and technical function, as well as making pronouncements regarding the convenience of signature, ratification and termination of conventions, treaties, pacts and agreements relating to industrial property”.

**Article 241.** The Judiciary is authorized to create special courts to settle questions relating to intellectual property.

**Article 242.** The Government will submit to the National Congress a bill with a view to promoting, whenever necessary, the harmonization of this statute with the policy for industrial property adopted by the other countries that are members of the MERCOSUL.

**Article 243.** This statute will enter into force on the date of its publication with respect to the matter contained in articles 230, 231, 232 and 239, and 1 (one) year after its publication with respect to the remaining articles.

**Article 244.** Statute #5,772 of December 21, 1971, Statute #6,348 of July 7, 1976, articles 187 to 196 of Decree-Statute #2,848 of December 7, 1940, articles 169 to 189 of Decree-Statute #7,903 of August 27, 1945 and other contrary provisions are revoked.
This text is an integral part of the Patent Application Examination Guidelines. The Guidelines set out the current understanding of the BRPTO on the content of patent applications. Other inherent exam topics are listed and discussed in the general guidelines.
CONTENTS OF PATENT APPLICATION

CHAPTER I. TITLE

1.01 The title of the Application must define the technical scope of the invention in a concise, clear and accurate manner, and must be the same for the request, the Specification, the summary and the sequence listings, if any. The Examiner must assess whether the title adequately represents the different claim categories. There is no need for all independent claims in the same category to be represented in the title.

Example: If an application requests more than one alternative for the same independent claim category, such alternatives may be represented together.

1.02 If the claims are subject to alterations in category, the Examiner must ascertain whether the title requests the corresponding alteration. In an examination opinion issuing a request for the title, the Examiner may suggest a new title.

CHAPTER II. SPECIFICATION

PRESENTATION MODE

2.01 The Examiner must ascertain whether the presentation mode of the Specification complies with the following requirements:

a. be initiated by the title;
b. be referred to a single invention or a group of inter-related inventions that constitute a single inventive concept;
c. have specified the technical field to which the invention is related;
d. have indicated the state of the art deemed relevant by the applicant for understanding the invention;
e. have disclosed the invention as claimed, in a manner whereby the technical problem and its solution may be understood, establishing any advantageous effects of the invention in terms of the relevant state of the art;
f. have clearly expressed its novelty and have presented the technical effect attained;
g. have listed the figures presented in the drawings, specifying their graphic representations, such as views, cross-sections, circuit layouts, block diagrams, flowcharts, graphs, etcetera;
h. have described the invention in a consistent, accurate, clear and sufficient manner, whereby a person skilled in the art may implement it, making mention to the reference signs shown in the drawings, if any and, when appropriate, using examples and/or comparative tables, relating them to the state of the art;
i. when appropriate, have stressed the best way of implementing the invention known by the applicant on the filing date, or the priority date, if any. The best mode of execution applies to all elements considered essential to the invention even the unclaimed ones.

Example: An invention addresses an elastomer seal and the respective treatment methods for the fabrication of this seal. Although not claimed, this method is deemed essential to achieving the specific characteristics presented by the seal, and must be described in the specification as, without a description of the method, the claimed seal cannot be implemented.

j. have indicated, in an explicit manner, if this is not inherent to the description or nature of the invention, whereby the invention may be used or produced by any type of industry.
2.02 The Examiner may allow a presentation other than the manner specified above, only when this allows a better understanding of the invention.

**STATE OF THE ART**

2.03 The Specification must include the state of the art pertinent to the invention, which may be useful for understanding the invention, as well as the search and the examination of the invention.

2.04 The documents mentioned as representative of the state of the art must be identified, whether found in patent or non-patent literature.

2.05 As a result of the examination, the Examiner may request the applicant to include documents on the state of the art in the Specification of the application, such as documents found during the search, for example, considering that the content of these documents does not extend beyond the original disclosure of the invention addressed in the application as originally filed.

**TECHNICAL PROBLEM TO BE SOLVED BY THE INVENTION AND PROOF OF THE TECHNICAL EFFECT ATTAINED**

2.06 The invention must be described in a manner that allows the technical problem to be understood, as well as the proposed solution. In order to comply with this condition, only details considered necessary for elucidating the invention should be included.

2.07 Pursuant to Rule #127/97 [item 15.1.2(e)], it is necessary for the invention to resolve technical problems, offering a solution to such problems and be endowed with a technical effect [item 15.1.2(f)]. It is thus necessary to clearly present the technical nature of the problem to be resolved, the proposed solution and the effect attained, in order to constitute an invention.

2.08 A patent application should not necessarily describe the best possible solution to the problem in question. The expression “technical problem” must be construed in a broad-ranging manner: This expression does not necessarily imply that a technical solution constitutes an advance on the state of the art. Thus, the problem may simply be seeking an alternative that could achieve the same outcomes through different technical paths.

2.09 Documents related to the state of the art, identified subsequent to filing, that is, during the search or displayed on subsidies exam, may mean that the technical problem addressed by the Application must be reformulated. In this case, provided that such reformulation could be deduced by a person skilled in the art and is inherent to the matter initially disclosed, based on the application as filed, such documents may be included in the specification, in order to underscore the contribution of the invention to the state of the art.

2.10 The word “inherent” requires that the matter not described is necessarily implicit in the application as filed, and that this would be recognized by a person skilled in the art. This characteristic of being inherent may not be established through probabilities or possibilities. The mere fact that something may result from a given set of circumstances is not sufficient.

2.11 The reformulation of the technical problem as addressed in the previous ¶ may not be included in the claim chart.
**INDUSTRIAL APPLICATION**

2.12 The specification must explicitly indicate the manner in which the invention could be used by industry, should this not be inherent to the specification or the nature of the invention.

**TITLE I. SUFFICIENCY OF DISCLOSURE**

2.13 Sufficiency of disclosure must be assessed on the basis of the specification, which must present the invention in a sufficiently clear and accurate manner, to the point that it could be reproduced by a person skilled in the art. The specification must contain sufficient conditions that ensure the materialization of the claimed invention.

2.14 The “person skilled in the art” for this purpose is deemed to be a person who is knowledgeable not only about the presentation of the invention as such, and its references, but is also endowed with general knowledge of the technique at the time when the application was filed. It is assumed that this person has the means available and the abilities required for routine work and experimentation usual in the technical field in question. There may be cases where it would be more appropriate to think in terms of a group of people, such as a production or research team. This may apply particularly to certain advanced technologies, such as computers and nanotechnology.

2.15 In this context, it is necessary to ensure that the application contains sufficient technical information that would allow a person skilled in the art to:

i. put the invention into practice as claimed, without improper experimentation; and

ii. understand the contribution made by the invention to the state of the art to which it belongs.

2.16 The description of the theoretical basis justifying the functioning and outcomes attained by the invention must be presented in the specification as a way of better understanding the invention, although this is not a determining factor for ensuring sufficiency of disclosure, as this criterion requires only the presentation of the description allowing the implementation of the invention by a person skilled in the art. In cases where this description is deemed essential for the search and analysis of the application, as well as for a better understanding of the invention, it must always be presented.

**§I. BIOLOGICAL MATERIAL FILING**

2.17 When the application addresses biological material that is essential for the practical materialization of the application, which cannot be described in the manner set forth in article 24 of the Brazilian IP Statute, and when not accessible to the public, the specification must be supplemented, even after the examination of the application, through filing the material at an institution authorized by the Brazilian IP Statute, or indicated in an international agreement.

2.18 Should there be no institution in Brazil that is authorized by the Brazilian IP Statute or indicated in an international agreement effective in Brazil, the applicant may file a biological material with any of the international filing authorities acknowledged by the Treaty of Budapest, necessarily doing so by the patent application filing date, and this data must be mentioned in the specification of the patent application.

**§II. SEQUENCE OF LISTINGS**

2.19 The applicant presenting a patent application whose purpose encompasses one or more sequences of
nucleotides and/or amino acids that are fundamental for the description of the invention must represent them in a sequence of listings in order to allow an evaluation of the sufficiency of disclosure addressed by Article 24 of the Brazilian IP Statute. Brazilian IP Statute Resolution 228/09 establishes the procedures for the presentation of the sequence of listings on electronic media, substituting item 16.3 of Rule #27/97.

**Matter Initially Disclosed in the Specification**

2.20 Article 32 of the Brazilian IP Statute establishes that for better clarification or definition of the Patent Application, the applicant may introduce alterations up to the request for examination, provided that they are limited to the matter initially disclosed in the application.

2.21 There is nothing preventing the applicant from introducing amendments to the specification, providing a better description of the state of the art, as well as eliminating incoherent aspects of the text, at any time.

2.22 The inclusion of data, parameters or characteristics of the invention not encompassed by the application originally filed constitute additional matter and, as such, may not be accepted.

**Example**: In a patent application addressing a chemical composition containing several ingredients, an additional ingredient added to this composition would be deemed to constitute an improper addition to the matter. Similarly, a patent application for an invention describing a bicycle frame without specifying the type of material would imply an addition of matter, if the applicant request an amendment describing such material as being aluminum, which is essential for the invention. In case of such amendment represent only the state of the art, it would be accepted.

**Example**: In an invention addressing a type of rubber without explicitly disclosing at any time, for example, that the rubber is elastic, an amendment to the specification mentioning this characteristic could be accepted without this constituting an addition of matter, as this characteristic is inherent to any rubber, for a person skilled in the art, at the time of filing.

2.23 Amendments to the specification resulting from receipt of an examination opinion drawn up by the Brazilian IP Statute must be examined. Should the applicant present voluntary amendments to the specification on this occasion, not arising directly from the examination, they must also be examined and will be accepted, provided that they are limited to the matter initially disclosed in the application.

2.24 After the request for examination, voluntary amendments to the specification must be accepted, provided that they are limited to the matter initially disclosed in the Application.

**Use of Proper Names, Registered Trademarks or Trade Names**

2.25 The use of proper names, registered trademarks, trade names or similar words is not permitted, when such words merely refer to the origin or a set of different products. If such a word is used, the product must be sufficiently identified, whereby the invention may be implemented by a persons skilled in the art, based on the information disclosed at the time of filing.

2.26 Exceptions occur when such words are accepted as standardized descriptive terms, having acquired a specific meaning, such as nylon or Teflon layer. In this case, such words are permitted with no need for supplementary identification, in terms of the product to which they are related.
**Reference Signs**

2.27 The reference signs used in the drawings must be mentioned in the specification and, if applicable, in the claim chart.

2.28 The specification and the drawings must be consistent among themselves, and the reference signs must be defined in the specification.

2.29 The reference signs must be uniform throughout the application.

**Terminology**

2.30 The specification must be clear, necessarily using terms acknowledged at the state of the art. Technical terms that are rarely used or specially formulated may be accepted, provided that they are adequately defined and there is no equivalent acknowledged at the state of the art.

2.31 The adoption of this criterion must be extended to encompass foreign terms, when there are no equivalent terms in Portuguese. Terms that have already an established meaning may not be used to meaning something different, in order to avoid confusion.

2.32 Terminology must be uniform throughout the application.

**Physical Values and Units**

2.33 When properties are used for characterization of the material, the relevant units must be specified, if quantitative considerations are involved. Should this be addressed through an established standard (for example, standard mesh sizes) and a set of initials or some similar abbreviation is used to refer to such standard, this information must be properly presented in the specification.

2.34 Units of weight and measure must be expressed through the International System of Units, with their multiples and sub-multiples, except for terms that are firmly established in specific technical areas such as: Btu, mesh, barrel, inches. When the unit used differs from the practice established for the sector and the International System of Units, the applicant must present the respective conversion to the International System of Units.

2.35 For geometrical, mechanical, electrical, magnetic, thermal, optical and radioactive indications, compliance is required with the provisions set forth in the current General Measurement Units Table established by the competent Brazilian entity.

2.36 Chemical formulas and/or mathematical equations, as well as symbols, atomic weights, specific units and nomenclature not addressed in the General Measurement Units Table established by the competent Brazilian entity must comply with established practice in the sector.

2.37 The terminology, symbols and unit system adopted must be uniform throughout the entire application.

**Generic Statements**

2.38 Generic statements in the specification implying that the extension of the matter submitted to the protection
may be expanded in a vague and not precisely defined manner constitutes an irregularity, under Article 24 of the Brazilian IP Statute.

2.39 More specifically, objections must be raised to any statement that refers to the extension of the protection in order to encompass the “spirit” of the invention. Objections must also be raised to a “combination of characteristics” or any statement implying that the invention addresses not only the combination as a whole, but also the individual characteristics or their sub-combinations.

**Reference Documents**

2.40 Documents mentioned as references in the patent application may be related to the state of the art or to a part of the disclosure of the invention. Reference documents from patent or non-patent literature related to the state of the art may be present in the application originally filed, or may be introduced at a subsequent date (see item 2.03).

2.41 When the reference document is related to the invention, the Examiner must initially consider whether the contents of the reference document are really essential for the implementation of the invention, as understood through article 24 of the Brazilian IP Statute:

a. if not essential, the commonplace phrase “that is included here for reference purposes” or any expression of this type may be maintained in the specification; and
b. Should the matter addressed in the reference document be essential to ensuring sufficiency of disclosure, the Examiner must request the suppression of the above-mentioned phrase, requiring the matter to be specifically included in the specification, as the specification of the application must be self-sufficient, meaning that it can be understood in terms of the essential characteristics of the invention with no reference to any other document.

2.42 This inclusion of essential matter or essential characteristics is nevertheless subject to the constraints established by article 32 of the Brazilian IP Statute, namely:

a. Protection was initially claimed for such characteristics, in a manner compliant with article 25 of the Brazilian IP Statute;
b. Such characteristics contribute to solving the technical problem underlying the invention;
c. Such characteristics clearly belong to the description of the invention presented in the application and thus to the content of the application as filed; and
d. Such characteristics are defined in an accurate and identifiable manner in all the technical information found in the reference document.

2.43 Should the reference document be essential for the implementation of the invention, and should it not be available to the public on the application filing date, it may be accepted as a reference only if available to the public by the application publication date. Should it not be available, the Examiner must query the sufficiency of disclosure of the application, under article 24 of the Brazilian IP Statute.

2.44 On an exceptional basis, should the application mention a document that has been published but is not accessible to the Examiner, and should the document be deemed essential for a correct understanding of the invention, whereby it would not be possible to conduct a meaningful search without being aware of the contents
of this document, the Examiner must issue a request for the applicant to present the document. In this case, should this reference document be written in a foreign language, this reference document must be accompanied by a translation into Portuguese.

2.45 Should the copy of this document not be presented promptly as required for compliance with this request, and should the applicant fail to convince the Examiner that the document is not essential to conducting a meaningful search, the Examiner must issue an examination opinion, under the insufficiency of disclosure of the application resulting from the non-availability of this document, pursuant to article 24 of the Brazilian IP Statute.

2.46 Should a document be mentioned in an application as originally filed, the relevant contents of the reference document must be deemed to form part of the content of the application, for the purpose of confirming prior filing against subsequent applications.

CHAPTER III. CLAIM CHART - CLAIMS

GENERAL

3.01 The application must contain one or more claims that must:

   i. define the matter for which protection is requested;
   ii. be clear and precise; and
   iii. be under the Specification.

3.02 Based on the matters set forth above, the number of independent and dependent claims must be sufficient to correctly define the object of the application.

NUMBERING

3.03 The claims must be numbered consecutively, in arabic numerals.

TITLE I. FORM, CONTENT AND TYPES OF CLAIM

PREAMBLE, CHARACTERIZING EXPRESSION AND CHARACTERIZING PART

3.04 As an invention generally consists of characteristics that are already known and new characteristics, in order to ensure easier understanding of what the invention represents, an independent claim must consist of:

   i. An initial part that corresponds to the title or part of the title corresponding to its respective category;
   ii. When necessary, a preamble presenting the characteristics already encompassed by the state of the art; and
   iii. Necessarily, the expression “characterized by,” followed by a characterizing part presenting the specific characteristics of the invention.

3.05 This separation between known elements and new elements is intended merely to facilitate this distinction, as it does not alter the range or scope of the claim, which will always be defined on the basis of the sum of the characteristics presented in the preamble and the characterizing part.
3.06 Attention must be paid to the fact that the novelty of the characteristics presented after the expression “characterized by” must always be established in relation to the set of characteristics taken as known and defined in the preamble.

3.07 Should the preamble define characteristics A and B as being associated, and the characterizing part define characteristics C and D, it does not matter whether C and/or D are known per se, but rather whether they are known in association with A and B, meaning not only with A or only with B, but with both of them. For instance, a machine with four distinct elements, A, B, C and D, and they are all known from the state of the art. This machine that is an association of these four elements, may present novelty and inventive step.

3.08 The formulation of the preamble may not be appropriate in a series of situations, when the invention addresses:

i. a specific combination of known components;
ii. Modification of known processes through the omission or substitution of a stage, in contrast to the addition of a stage;
iii. Modification of known products through the omission or substitution of an element, in contrast to the addition of an element; and
iv. A complex system of parts that are functionally inter-related, with the essence of the invention under this inter-relationship.

3.09 For the specific case of process patents, the set of sequential steps is what correctly defines the request. Thus, if some of the steps in this process form part of the state of the art, it is possible that it would not be feasible to transfer them individually to the preamble without burdening the claimed process with disorder and a lack of logic. In this case, the correct positioning of the expression “characterized by” must be noted.

**Technical Characteristics**

3.10 Claims must be worded as a function of the “technical characteristics of the invention,” which means that claims may not contain characteristics associated with commercial advantages or other non-technical aspects.

**Example:** A claim describing a sneaker with a sole and means for attaching the sole must present in the specification the means that could be used for this purpose, such as buttons, Velcro etcetera.

3.11 In a “means plus function” type of claim, the patent application must present in its specification at least one type of materialization that presents the structural elements used to attain such functions.

3.12 It is not necessary for each of the characteristics of the invention to be expressed only in terms of their structural elements, as functional characteristics may also be included, provided that a person skilled in the art would have no difficulty in arranging such elements in order to perform the function, at the time of the invention.

3.13 Item 15.1.3.2(k) of Rule #127/97 establishes that claims are not accepted with segments that explain the functioning, advantages and simple use of the object. Consequently, merely explanatory segments must be distinguished from relevant functional characteristics.

3.14 Claims addressing the use of the invention, meaning its technical application as set forth in the specification, are permitted.
FORMULAS AND TABLES

3.15 Claims and their specifications may contain chemical or mathematical formulas, but not drawings. Claims may contain tables, when the use thereof clarifies the matter addressed by the application.

TYPES OF CLAIMS

3.16 There are only two types of claims: “product claims,” which address a physical entity, and “process claims,” which encompass all activities in which some material product is needed to perform the process. The activity may involve material products, electricity and/or other processes, such as control processes.

3.17 Examples of the “product claims” categories are: product, device, object, article, item of equipment, machine, apparatus, cooperative equipment system, compound, composition and kit; and “process claims”: process, use and method.

3.18 For all effects, process and method are synonymous.

3.19 A single application may present claims in one or more categories, provided that they are linked by a single inventive concept.

TITLE II. FORMULATION OF CLAIMS

3.20 The formulation of claims must:

a. Begin with the title or part of the title corresponding to its respective category, containing the expression “characterized by” only once;
b. Define clearly and accurately, in a positive manner, the technical characteristics to be protected thereby;
c. Be fully grounded in the specification;
d. Except when absolutely necessary, no references should be made to the specification or the drawings when describing the characteristics of the invention, such as “as set forth in the specification” or “as shown in the drawings”;
e. When the application contains drawings of its technical characteristics, this must be accompanied by the respective reference indicators in brackets as shown in the drawings, if deemed necessary for a proper understanding thereof, noting that such reference indicators impose no constraints on the claims;
f. Be worded with no bullet point interruptions;
g. Have no segments explaining the functioning, advantages and simple use of the object, as this will not be accepted.

§I. INDEPENDENT CLAIMS

3.21 Independent claims are intended to protect specific essential technical characteristics of the invention, in its comprehensive conceptualization.

3.22 There must be at least one independent claim for each claim category.

3.23 The Examiner must bear in mind that the presence of claims of several categories worded differently, but
apparently with similar effects, is an option of protection for the applicant that the Examiner may not oppose through a rigorous approach, but should rather focus on an unnecessary proliferation of independent claims.

3.24 Each independent claim must correspond to a specific set of characteristics that are essential to the materialization of the invention and only will be allowed more than one independent claim in the same category if such claims define different sets of features and essential alternatives to the invention, linked by the same inventive concept.

3.25 Inter-related independent claims in different categories that are linked by the same inventive concept, where one of the categories is specially adapted to another, must be drawn up in a manner that clearly presents their interconnection, meaning that phrases are used in the initial part of the claim such as: “device for performing the process defined in Claim…,” “Process for obtaining the product defined in Claim…”

3.26 Examples of inter-related claims are:

   i. Plug and socket, for interconnection;
   ii. Transmitter and its respective receivers;
   iii. Intermediate and end chemical products;
   iv. Gene, gene construction, host, protein and medication; and
   v. Product and product use.

3.27 Between their initial part and the expression “characterized by,” independent claims must contain a preamble, when necessary, describing the characteristics that are essential for to defining the claimed matter and that are already encompassed by the state of the art (see item 3.04).

3.28 After the expression “characterized by,” the essential and specific technical characteristics must be defined for which protection is desired, together with the aspects addressed in the Preamble (see item 3.04).

3.29 Independent claims may underpin one or more dependent claims, being grouped in the order corresponding to the title of the application.

**§II. Dependent Claims**

3.30 Dependent claims are those that include all the characteristics of other prior claim(s), and define detailed descriptions of these characteristics and/or additional characteristics that are not deemed to constitute the essential characteristics of the invention, necessarily containing an indication of the dependence to these claim(s) and the expression “characterized by”;

3.31 Dependent claims may not extend beyond the boundaries of the characteristics encompassed by the claim(s) to which they refer;

3.32 Dependent claims must define, their links of dependence accurately and comprehensively, with no wordings being accepted such as “in compliance with one or more claims…,” “in compliance with the preceding claims ….” Wording such as “compliance with any one of the previous claims” and “in compliance with one of the previous claims” is accepted;

3.33 Any dependent claim that refers to more than one claim, meaning a multiple dependence claim, must be linked to
these claims in an alternative or cumulative manner, provided that the links of dependence for the claims are structured in a manner that allows an immediate understanding of the possible combinations resulting from such dependence;

3.34 Multiple dependence claims, whether alternative or cumulative, may underpin any other multiple dependents claim, provided that the links of dependence for the claims are structured in a manner that allows an immediate understanding of the possible combinations resulting from such dependence.

3.35 All dependent claims referring to one or more previous claims must be grouped in a manner that ensures a concise structure for the claim chart.

Title III. Clarity and Interpretation of Claims

General

3.36 The condition that claims must be clear is applicable to individual claims as well as to the claim chart as a whole. The clarity of the claims is of the utmost importance, as they define the matter to be addressed by the protection. Thus, the meaning of the terms in the claims must be clear to a person skilled in the art, based on the wording of the claim and under the specification and the drawings, if any. In view of the differences in the scope of the protection attained by various claim categories, the Examiner must ensure that the wording of the claim is clear for the category it represents.

3.37 Claims are interpreted on the basis of the specification and drawings (and sequence listings, if any), as well as in the general knowledge of a person skilled in the art, on the filing date. When the specification defines any particular term that appears in the claim, this definition is used to interpret the claim. Claims may not be limited to what is explicitly stated in the specification and shown in the drawings, and neither may claims be bound by the scope of the examples of the claimed invention presented in the specification, compliance with the limits imposed by article 25 of the Brazilian IP Statute.

3.38 For Markush-type claims, the Examiner must ensure that the processes for obtaining the object as described in the specification materially underpin the preparation of all the claimed compounds, meaning that the examples must be representative of all claimed compound classes.

3.39 For cases in which a person skilled in the art, is not be able to materialize the invention as claimed, or should this require improper experimentation efforts, generic claims must be limited to the forms of implementation mentioned in the specification.

Inconsistencies - Under the Specification and Drawings

3.40 Any inconsistencies noted between the specification on the claim chart must be avoided, as this throws doubt on the extent of the protection and indicates that the claim chart is not clear, or is not properly under the specification. Such inconsistency can be one of the following types:

i. Simple verbal inconsistency – When the specification is necessarily limited to a specific characteristic, but the claims fail to comply with this constraint, the inconsistency may be remedied through adapting the claim chart to the specification, thus curtailing its scope, pursuant to article 25 of the Brazilian IP Statute, with special
attention to article 32 of the Brazilian IP Statute. Should the specification refer to a specific characteristic, such as screws, for example, and should the claim chart mention means of fixation in general, and should the Examiner find that the invention is necessarily not limited to screws, it will be understood that there is an inconsistency between the specification and the claim chart. Another situation occurs when the claim presents a constraint, but the report fails to lay any particular stress on this characteristic. In this case, there is no inconsistency between the specification and the claim chart.

ii. Inconsistency related to apparently essential characteristics - Should it be generally known at the state of the art or constitutes established expertise, or is implicit in the invention, that a certain technical characteristic in the specification is considered as essential for the materialization of the invention, but this is not mentioned in an independent claim, this claim must not be allowed by the Examiner, under article 25 of the Brazilian IP Statute.

**Generic Statements**

3.41 Generic statements in the specification, as well as in the claim chart, implying that the scope of the protection may be extended in a vague manner that is not precisely defined, constitute an irregularity, pursuant to article 25 of Brazilian IP Statute. More specifically, objections must be raised to any statement referring to the scope of the protection being extended in a manner that encompasses the “spirit” of the invention. Objections must also be raised to claims addressing a combination of characteristics, for any statement that seems to imply that the protection claimed covers not only the combination as a whole, but also individual characteristics or their sub-combinations.

**Essential Characteristics**

3.42 An independent claim must explicitly specify all the essential characteristics needed to define the invention, unless such characteristics are implicit through the generic terms used. In other words, “bicycle” need not mention the presence of wheels.

3.43 Should the claim refer to a process for obtaining a product of the invention, the process as claimed must ensure that, when implemented in a manner deemed reasonable for a person skilled in the art, its final outcome must necessarily be that specific product. Otherwise, there would be an internal inconsistence and consequently a lack of clarity in the claim.

3.44 Should a claim address a product where type is well known, and the invention lies in the modification of certain aspects, it is sufficient for the claim to identify the product clearly, specifying where it is modified and in what manner this occurs. Similar remarks are applicable to claims for a device.

3.45 The patentability of the invention depends on the technical effect obtained, whereby claims must be drawn up in a manner that includes all the technical characteristics that are considered as essential to attaining the technical effect, contained in the specification.

**Use of Relative and/or Imprecise Terms**

3.46 The use of relative terms such as “large,” “broad,” “strong,” among others is not permitted in a claim, except for meanings that are well established in a specific technique, such as “high-frequency” for an amplifier, when this is the intended meaning. Any relative term that does not have this meaning must be replaced by a more precise term or by another that has already been described in the specification, as filed.
3.47 Imprecise words or expressions, such as “about,” “substantially,” “approximately” among others are not permitted in the claim, regardless of whether they are deemed essential to the invention.

3.48 Should relative terms or imprecise phrases be used in the claim, the Examiner must declare lack of clarity. Counter-arguments presented by the applicant alleging that elements missing from the text are part of the state of the art will not be accepted, as problems related to a lack of clarity will remain. Furthermore, the inclusion of these elements in the text is considered additional matter and is consequently not permitted.

**“Consisting of” versus “Comprising”**

3.49 The terms “comprising” and “consisting of” as well as derivatives thereof, are considered closed terms of definition for the invention. Thus, if the claim addresses a “chemical composition comprised of components A, B and C,” the presence of any additional components is excluded.

3.50 The terms “comprehend,” “contain,” “encompass” and “include,” together with their derivatives, are considered open terms of definition for the invention, meaning that in the above example, the phrase “comprehends components A, B and C” is not limited to only these elements, and may be accepted, provided that such elements are essential for the materialization of the invention.

**Optional Characteristics**

3.51 Expressions such as “preferably,” “for example,” “such as” and “more particularly,” among others must be examined with special attention in order to ensure that they do not introduce any ambiguity. These expressions do not impose a limited effect on the scope of a claim, meaning that the characteristic following any expressions such as these must be considered as fully optional.

**Example:** In a process claim mentioning a temperature parameter “… In a range of 80°C – 120°C, preferably 100°C,” the word “preferably” does not introduce any ambiguity to this claim.

**Registered Trademarks**

3.52 Registered trademarks or similar expressions should not be permitted in claims, as there are no guarantees that the product or characteristic associated with a trademark or similar might not be modified during the validity of the patent. On an exceptional basis, they may be authorized if the use thereof is unavoidable, and if they are generally recognized as having a specific meaning.

**Definition of the Matter Presented for Protection in Terms of the Outcomes to be Attained**

3.53 As a general rule, claims that define an invention through the outcomes to be attained should not be permitted, particularly if they refer only to claiming the technical problem involved. However, they may be permitted if the invention can be defined only in such terms, or if it cannot be defined more precisely without improperly curtailing the scope of the claims, and if the outcome can be directly and positively checked through tests and procedures that are properly specified in the specification or that are known to a person skilled in the art, requiring no improper experimentation.

3.54 A claim addressing a material that would be able to extinguish cigarette flames and where specification
presents a chemical composition for this material would not be accepted, as the material could consist of its chemical composition, rather than the outcomes to be attained by the invention, mentioned as an example.

3.55 It must be noted that the requirements set forth above for defining the matter presented for protection in terms of the outcomes to be attained differs from those for the definition of the matter presented for protection in terms of functional characteristics (see item 3.97).

**Definition of the Matter Presented for Protection in Terms of Parameters**

3.56 Parameters are characteristic values that may be directly measurable properties, such as the melting point of the substance, the resistance to bending of steel, the resistance of an electrical conductor, or maybe defined as mathematical combinations containing assorted variables set forth in formulas.

3.57 The characterization of a product through its parameters may be permitted only in cases where the invention cannot be adequately defined in any other manner, and provided that these parameters can be clearly and reliably determined, through either the indications presented in the specification or through objective procedures that are commonplace at the state of the art. This also applies to a process-related characteristic that is defined through parameters.

3.58 Due to the possibility of the formation of different crystal networks, the polymorphs of a single chemical substance may have different physicochemical properties, such as melting points, chemical reactivity, apparent solubility, dissolving rate, mechanical and optical properties, vapor pressure and others. Consequently, they must always be defined through their physical and chemical characteristics, mentioned as an example.

3.59 Cases in which uncommon parameters are used, even if sufficiently described, are not acceptable at first sight, due to a lack of clarity, as no significant comparison with the previous technology can be drawn. In these cases, applicant must prove, in the specification, the balance between these uncommon parameter(s) as used, and that or those used at the state of the art, which does not constitute additional matter.

3.60 Cases in which the method and means of measurement used for the parameters must also be presented in the claim are addressed in item 3.61.

**Methods and Means of Measurement for Parameters Mentioned in the Claims**

3.61 The invention must be fully defined in the claim. In principle, the method of measurement is necessary for a clear definition of the parameter. Nevertheless, the methods and means of measurement for the parameter values are not necessary in the claims, when:

i. the description of the method is so long that its inclusion would undermine the clarity of the claim due to a lack of concision or would make it hard to understand;

ii. a personskilled in the art, would know which method to use, because there is only one method, for example, or because a specific method is used routinely; or

iii. all known methods achieve the same results, within the measurement accuracy limits.

3.62 However, in all other cases, the methods and means of measurement must be included in the claims, as they define the matter for which protection is sought.
**Product Claims by Process**

3.63 Product claims defined in terms of a manufacturing process are permitted only if the products comply with patentability requirements, meaning that they are new and inventive, and provided that the product cannot be described in any other way. A product is not deemed to be new simply because it is produced through a new process. With regard to the analysis of novelty, a claim for product X obtained through process Y lacks novelty when a prior filing for this same product X is found, regardless of how it is obtained.

3.64 A claim defining a product in terms of the process must be construed as a product claim. For example, the claim may be presented as “product X characterized by being obtained through process Y.” Regardless of whether the words “obtain,” “obtained,” “obtained directly,” or an equivalent expression are used in the product claim by process, the claim is still focused on the product as such, conferring full protection on the product. This type of claim may be accepted only when it is not possible to define the product per se in an adequate manner, but only through the manufacturing process.

3.65 Consider a case in which a compound material is prepared that includes a new sintering step, and the resulting product is endowed with notable characteristics consisting of greater mechanical resistance, compared to the state of the art for materials with the same nominal composition, although the applicant is unable to describe the material per se. In this case, the product may be described in terms of the product obtained through the process.

**Definition through Reference to Use or Another Object**

3.66 When a product claim (see item 3.16) defines the invention through reference to characteristics related to the use thereof, this may result in a lack of clarity.

3.67 Consider a case in which the claim does not define just the actual product, but also specifies its relationship to a second product that is not part of the claimed product.

*Example:* The head of an engine, in which the former is defined by the characteristics of its location on the latter.

3.68 Before considering a constraint on the combination of the two products, it must be recalled that the applicant has the right to independent protection for the first product.

*Example:* A claim for a “head connected to an engine” may not be modified to a “head connectable to an engine,” nor for the head alone, as this is deemed to breach Article 32 of the Brazilian IP Statute, although this change is supported in the specification initially disclosed.

3.69 On the other hand, as the first product may often be produced and sold without the second product, a claim for a “head connectable to an engine” initially requested, may be modified to a “head connected to an engine” or for the head itself. Should it not be possible to provide a clear definition of the first product alone, then the claim must address a combination of the first and second products: “head connected to an engine” or “engine with a head.”

3.70 Defining the dimensions and/or the shape of a first object in an Independent Claim may also be permitted, through general reference to the dimensions and/or shape of a second object that is not part of the first entity claimed, that is related to it through use. This is applicable especially when the size of the second object is standardized in some way.
Example: In the case of a support rack for a vehicle number plate, where the support frame and the fixation elements are defined in terms of the external shape of the plate.

3.71 However, references to second entities that cannot be viewed as standardized may also be sufficiently clear in cases where a person skilled in the art, would have little difficulty in inferring the constraint resulting from the field of protection for the first object.

Example: In the case of a roof for a circular farm stall, where the length and width of the roof are defined on the basis of the dimensions of the stall.

3.72 There is no need for such claims to contain the exact dimensions of the second entity, nor to refer to a combination of the first and second entities. Specifying the length, width and/or height of the first entity, with no reference to the second entity, would lead to an improper constraint on the scope of the protection.

The word “in” or “on” (“em” in Portuguese)

3.73 In order to avoid ambiguity, the word “in” or “on” (“em” in Portuguese) must be examined with special attention in claims where it defines relationships among different physical entities (product, equipment) or among entities and activities (process, use) or among different activities. Examples of claims using the word “in” or “on” (“em” in Portuguese) in this context are:

   i. Engine head “in” a four stroke engine, comprised of…;
   ii. Tone dialing detector “in” a telephone with an automatic dialer, with the tone dialing detector comprised of…;
   iii. Method for controlling current and voltage “on” a process using means to power an electrode for an arc welding item of equipment, comprised of the following stages:…; or
   iv. Fine-tuning X… “on” a process/system/item of equipment etcetera, comprised of….

3.74 For claims of the type indicated by examples (i) to (iii), the emphasis is on the full functionality of the sub-units, namely: “engine head, tone dialing detector, method for controlling arc welding current and voltage” instead of a complete unit within which the sub-unit is contained: four-stroke engine, telephone, welding process. This may constitute a lack of clarity, if the requested protection is limited to the sub-unit alone, or if the unit as a whole must be protected.

3.75 As a matter of clarity, claims of this type must address either “a unit with” or “comprised of a sub-unit,” namely the “four-stroke engine with a head” or just for the sub-unit, specifying its purpose: “head for a four-stroke engine.”

3.76 In claims of the type indicated through example (iv), the use of the word “in” or “on” does not clearly indicate whether protection is required only for the improvement, or for all the characteristics defined in the claim. Here also, it is essential to ensure that the wording is clear. However, claims such as: “use of the substance X comprised of being a composition of paint or varnish” are acceptable when based on a second use.

Use Claims

3.77 For examination purposes, a “use” claim as expressed in “use of substance X as an insecticide,” must be deemed equivalent to a “process” claim, such as “a process for killing insects using substance X” or also “use
of an alloy X to manufacture a specific part.” Thus, a claim in the indicated manner may not be construed as directed to substance X, which is known, but rather to its intended use as defined, namely as an insecticide, or for manufacturing a specific part. However, a claim addressing the use of a process is equivalent to a claim addressing the same process.

3.78 Independent claims such as a “product characterized by use” whether product is already known at the state of the art, are not accepted due to a lack of novelty. Should a product not be known at the state of the art, such wording of a claim is not accepted due to a lack of clarity, pursuant to article 25 of the Brazilian IP Statute, as the product must be defined in terms of its technical characteristics (see item 3.10).

3.79 In the pharmaceutical area, claims involving the use of chemical and/or pharmaceutical products for the treatment of a new disease use a format that is conventionally called the Swiss formula:

“Use of a formula X compound, comprised of being for the preparation of a medication to treat disease Y.”

3.80 It is stressed that this type of claim confers protection for use, but does not confer protection on the method of treatment, which is not considered an invention, pursuant to item VIII of article 10 of the Brazilian IP Statute. Claims of the “useful treatment,” “process/method for treatment,” “administration for treatment,” or their equivalents, constitute treatment method claims and are consequently not considered inventions, pursuant to item VIII of article 10 of the Brazilian IP Statute.

REFERENCES TO THE SPECIFICATION OR DRAWINGS

3.81 With regard to the technical characteristics of the invention, claims may not refer to the specification or drawings, such as “as described in part… of the specification” or “as illustrated in Figure 2 of the drawings.”

REFERENCE SIGNS

3.82 When the application contains drawings, the technical characteristics defined in the claims must be accompanied by the respective reference signs, shown in brackets, as presented in the drawings, should this be deemed necessary for a proper comprehension thereof, on the understanding that such reference signs impose no constraints on the claims. Should there be a large number of alternatives for a single characteristic, only the reference signs needed to understand the claim should be included.

3.83 Reference signs, numbers and/or letters must be included not only in the characterizing part, but also in the preamble of the claims, provided that they accurately identify the elements in the drawings to which reference is made.

3.84 Texts associated with reference signs in the claims are not accepted in brackets. Phrases such as “means of fixation (screws 13, nail 14)” or “valve assembly (valve seat 23, valve element 27, valve seat 28)” are special characteristics to which the concept of reference signs is not applicable. Consequently, it is not clear whether the characteristics added to the reference signs impose constraints. Along these lines, the correct mention must be, for example: “the hose (4) is connected to the valve (10)” instead of “the hose is connected to the valve” or “4 is connected to 10.”

3.85 The lack of clarity also arises through phrases in brackets that do not include reference signs, such as: “brick
(concrete), molded.” In contrast, phrases in brackets with a generally accepted meaning are acceptable, such as: “(meta)acrylate,” which is a known form that encompasses acrylate and meta-acrylate. The use of brackets in chemical or mathematical formulas is also acceptable.

3.86 However, the opposite may be permitted, meaning that the drawings may present more reference signs than those contained in the claim chart.

**NEGATIVE LIMITATIONS**

3.87 Each claim must define in a clear, accurate and positive manner the technical characteristics to be protected thereby, avoiding expressions that result in a lack of definition for the claim.

3.88 However, negative constraints may be used only if the addition of positive characteristics in the claim does not clearly and concisely define the object for which protection is requested, or if such addition unduly curtails the scope of the application.

**Example**: Process for the production of expandable polystyrene (EPS) in the shape of beads through the polymerization of styrene in aqueous suspension in the presence of suspension stabilizers and polymerization starters soluble in conventional styrene … characterized by the fact that the polymerization is conducted in the absence of a chain transfer agent.

**Example**: Formula 1 compound, characterized by R1 being halogen, with the exception of R1 being chlorine.

§I. GROUNDS IN THE SPECIFICATION - ARTICLE 25 OF THE BRAZILIAN IP STATUTE

**GENERAL REMARKS**

3.89 Article 25 of the Brazilian IP Statute stipulates that claims must be under the specification, describing the specific characteristics of the application and also defining in a clear and accurate manner the matter for which protection is requested. This means that the matter addressed by each claim must be under the specification, with the scope of the claims not extending beyond the contents of the specification and drawings, if any, based on the contribution to the state of the art.

**LEVEL OF GENERALIZATION IN A CLAIM**

3.90 The appropriate wording of a claim must comply with the condition of precision stipulated in article 25 of the Brazilian IP Statute. Most claims are generalizations of one or more specific examples. The level of generalization permitted is an issue that must be analyzed by the Examiner in each case, in the light of the pertinent state of the art.

3.91 An invention opening up an entirely new field has the right to more generalities in the claim than another addressing advances in a technology that is already known.

**OBJECTION TO THE LACK OF GROUNDS**

3.92 A claim presented in a generic manner, meaning that it addresses an entire class, such as for materials or
machines, may be accepted despite its broad range, if there are any grounds related thereto in the specification. Whenever the information provided does not seem sufficient to allow a person skilled in the art, to implement the matter claimed using routine experimentation or analysis methods, the Examiner must raise an objection, requesting the applicant to present arguments showing that the invention may in fact be promptly applied on the basis of the information presented in the specification or, in the absence thereof, limit the claim in this manner.

3.93 Once the Examiner has established that a broad-ranging claim is not supported by the specification, the burden of demonstrating the contrary falls on the applicant. In this case, the Examiner may seek support in a published document in order to provide grounds for his reasoning.

3.94 The issue of grounds is illustrated by the following examples:

i. A claim addresses a process for treating all plant seedlings species by subjecting them to a controlled cold shock, in order to produce specific outcomes, while in the specification, this process is applied only to a single plant species. As it is well known that plants vary widely in their characteristics, there are well-founded reasons to believe that the process is not applicable to all plant seedlings. Unless the applicant supplies convincing evidence that the process is nevertheless suitable for general use, it must limit the claim chart in the application to the plant species mentioned in the specification. Merely stating that the process is applicable to all plant seedlings is not sufficient; ii. A claim refers to a specific method for treating “synthetic resin moulds” in order to obtain certain changes in the physical characteristics of the resin. All the examples described are related to thermoplastic resins, and the method seems to be inadequate for thermofixed resins. Unless the applicant can demonstrate that the method is nevertheless applicable to thermofixed resins, it must limit its claim to thermoplastic resins; and

iii. A claim refers to fuel oil compositions that have a specific desired property. The specification provides grounds for a manner of obtaining fuel oils with this property, achieved through the presence of defined quantities of a specific additive. No other way of obtaining the fuel oils with the desired properties is described in the Report. The claim makes no mention of the additive. In this case, the claim is not fully under the specification.

Lack of Grounds versus Insufficiency of Disclosure

3.95 It must be noted that, despite an objection based on a lack of grounds constituting an objection under article 25 of the Brazilian IP Statute, it may often be deemed to constitute an objection based on insufficiency of disclosure of the invention, pursuant to article 24 of the Brazilian IP Statute (see item 2.13), as shown in the examples presented in item 3.92. In this context, the objection lies in the fact that the patent application as disclosed is insufficient to allow a person skilled in the art to implement the “invention” throughout the entire field claimed, although sufficient for a more restricted “invention.” Compliance with both conditions is required in order to validate the principle that the wording of the claim must be supported on the specification of the patent application.

3.96 It has to be observed that the sufficiency of disclosure of the invention must be ascertained only in the specification, while article 25 refers to the grounds for the claim chart in the specification.

Definition in Terms of Function

3.97 A claim may define a characteristic broadly, in terms of its function, meaning as a functional characteristic, even when only one example of the characteristic is given in the specification, if a person skilled in the art feels that other means may be used for the same function (see also item 3.10 and 3.53).
3.98 The phrase “means of detecting the terminal position” in a claim may be provided with grounds through a single example that is comprised of a cut-off switch, as it is clear to a person skilled in the art that a photo-electric cell or an extensometer may also be used.

3.99 However, if the entire content of the application conveys the impression that a function must be performed in a certain manner, with no indications that alternative means are foreseen, and the claim is worded in such a way that it encompasses other means, or all means, of performing a function, then such claim is not acceptable. In this case, the specification does not offer support for the claim chart when it merely affirms in vague terms that other means may be used, if there is no clear definition of what they might be or how they might be used, thus breaching article 25. It is thus necessary to reword the claim, in order to limit its scope.

**SUBJECT MATTER PRESENTED IN THE CLAIM CHART AND NOT MENTIONED IN THE SPECIFICATION**

3.100 When a subject matter, object of protection is clearly disclosed in a claim submitted in the application as filed, but is not mentioned in any part of the specification, such subject matter may be included in the specification, provided that the contents thereof comply with article 24 of the Brazilian IP Statute.

3.101 The opposite situation, when a subject matter is contained in the specification and is not claimed up to the request for examination of the application, it may not then be claimed, except for restricting the claim chart.

**§II. UNITY OF INVENTION - ARTICLE 22 OF THE BRAZILIAN IP STATUTE**

**GENERAL REMARKS**

3.102 The patent application must refer to a single invention or a group of inventions that are inter-related in a manner that constitutes a single inventive concept. When a patent application refers to a group of inventions that are inter-related in a manner that constitutes a single inventive concept, this may give rise to a plurality of independent claims in the same category, provided that they define different sets of alternative characteristics that are essential to the implementation of the invention (see item 3.21).

3.103 A single inventive concept or the unity of the invention is understood as consisting of several claimed inventions that present a technical relationship among themselves, represented by one or more special technical characteristics that are the same or corresponding for the claimed inventions.

3.104 The expression “special technical characteristics” refers to the technical characteristics that constitute a contribution to the state of the art and that are common or correlated to each of the claimed inventions. Once the special technical characteristics have been identified for each of the inventions, it must be determined whether or not there is a technical relationship among the inventions conferred by the above-mentioned special technical characteristics.

3.105 It must be stressed that, in an initial analysis, the unity of the invention must be considered among the independent claims presented in the patent application.

3.106 Should there be a lack of novelty or inventive step in an independent claim, the other dependent claims must be analyzed not only in terms of merit, but also for the existence of a common inventive concept (see also item 3.135).
Whenever an application fails to present the unity of the invention, the Examiner must raise an objection based on article 22 of the Brazilian IP Statute.

**Special Technical Characteristics**

3.108 The inter-relationship among the inventions stipulated by article 22 of the Brazilian IP Statute must be a technical relationship, that is expressed in the claims in terms of the same or corresponding special technical characteristics. In any claim, the expression “special technical characteristics” means one or more characteristics that define a contribution made by the claimed intervention as a whole to the state of the art, construed on the basis of the specification and the drawings, if any. With the specific technical characteristics of each invention identified, it is necessary to determine whether or not there is a technical relationship among the inventions, and whether this relationship involves these special technical characteristics or not. There is no need for the special technical characteristics of each invention to be the same. The required inter-relationship may be found among corresponding special technical characteristics.

*Example:* In a specific claim, the special technical characteristic that provides resilience is a metal spring, while in another claim, it is a rubber block.

3.109 Inter-related elements must be specially adapted to each other. Should these elements have other applications, and if the above-mentioned relationship is merely one among several possibilities, it is felt that this does not constitute the inter-relationship needed to underpin the unity of the invention.

*Example:* A claim addressing non-slip artificial grass is presented together with another claim for a soccer ball made from a material that is particularly suitable for this type of pitch, which may also be used on other types of grass or pitches. In this case, it is felt that there is no unity of invention, despite the ball presents a better performance on the specific pitch as mentioned.

3.110 A plurality of independent claims in different categories may constitute a group of inventions that are inter-related among themselves in a manner that forms a single inventive concept. The following combinations of claims in different categories are permitted in a single application, as shown in the following examples:

i. an Independent claim for a specific product, an independent claim for a process specially adapted for the fabrication of the product in question, and an independent claim for a use of the product in question; or

ii. an independent claim for a specific process and an independent claim for a device or means specifically designed to implement the process in question; or

iii. an independent claim for a specific product, an independent claim for a process specially adapted for the fabrication of the product in question, and an independent claim for a device or means specifically designed to perform this process.

3.111 In a claim of the type indicated by example (i), the process especially adapted for the fabrication of the product, if the process results in the claimed product, meaning that if the process is really appropriate for attaining the claimed product and consequently defines a special technical characteristic between the claimed product and process. A fabrication process and its product may not be deemed to lack unity of invention due solely to the fact that the fabrication process is not limited to the fabrication of the claimed product.

3.112 For a claim of the type mentioned in example (ii), the device or means are specifically designed to perform
the process, the device or means is appropriate to perform the process and thus defines a special technical characteristic between the claimed device or means and the claimed process. On the other hand, it is irrelevant whether the device or means can or cannot be used for performing another process, or whether the process can also be performed using alternative devices or means.

3.113 Unity of invention may be found in an application presenting claims in one or more different technical fields, provided that there is a common or corresponding “special technical characteristic” between these claims.

**Example:** An application presents an independent claim for a polymer G, as well as another independent claim for a type of artificial grass made from the polymer G, for use on soccer pitches. In this case, although involving different technical fields, there is a unity of invention in the application, as the polymer G is a “special technical characteristic” that is common to these claims.

3.114 An application may contain more than one independent claim in the same category only if the subject matter presented for protection involves one of the following situations:

i. a plurality of inter-related products;
ii. different uses for a product or item of equipment; or
iii. different sets of alternative characteristics that are essential for the implementation of the invention, connected through the same inventive concept.

3.115 Furthermore, it is essential that a single general inventive concept interconnects the claims in various categories. The presence in each claim of expression such as “specially adapted” or “specially designed” does not necessarily imply that a single general inventive concept is present.

**Lack of Unity of Invention, A Priori or Posteriori**

3.116 The lack of unity of invention may be evident directly a priori, meaning considering the claims with no search for prior art documents, or may appear only a posteriori, meaning after the state of the art has been taken into consideration, consisting of documents that may be presented in the application, as well as those found during the search.

3.117 In a posteriori analysis of the unity of invention, if one or more documents constituting the state of the art pertinent to the invention show that the special technical characteristic is known, the independent claims must be analyzed for the existence of some other special technical characteristic that is common among them (see also item 3.135 for dependent claims).

3.118 A processing flowchart illustrating the analysis of the unity of an invention is presented in Appendix I of these Guidelines.

3.119 Should an application be deemed to lack unity of invention a priori, this must be reported by the Examiner through a notification in an examination opinion, with remarks on how to clearly and accurately identify the different unities of invention found in the application, or unified and interconnected groups of inventions, notifying the applicant of the need to exclude claims extending beyond the unity of the invention and/or the division of the application, rather than article 22 of the Brazilian IP Statute [item (i) of the flowchart]. In this case, a search
report must be issued on the basis of the first unity of invention claimed. The Examiner must await a reply from the applicant, after which he may:

i. reject the application due to a lack of unity and the absence of technical grounds provided by the applicant to justify the existence of the unity of invention and the application with no modifications; or
ii. continue with an examination of the application, should the applicant present convincing arguments for the existence of unity of invention, or should the claim chart have been limited to a single inventive concept.

3.120 Having considered the existence of unity of invention a priori through identifying the special technical characteristic found among the claims, the Examiner must proceed with the search for this characteristic among the independent claims [item (ii) of the flowchart]. Should this characteristic not be known at the state of the art, the application presents unity of invention a posteriori, with the Examiner necessarily supplementing the search for the entire claim chart [item (iii) of the flowchart], and then undertaking an examination of the merit of the application [item (iv) of the flowchart]. Should this characteristic be known at the state of the art, the Examiner must decide whether the search conducted was sufficient to encompass all the claimed subject matters addressed in the claim chart [item (v) of the flowchart]. If not, the application does not present unity of invention a posteriori, with the Examiner notifying the applicant as stipulated in article 22 of the Brazilian IP Statute [item (vi) of the flowchart] and presenting a search report, proceeding in the same manner as for a lack of unity of invention a priori, conducting the search [item (i) of the flowchart].

3.121 The lack of unity of invention may not be raised nor pursued on the basis of a narrow, literal academic approach. This is particularly valid in cases in which the Examiner notes that additional efforts allocated to the application search are limited [item (iv) of the flowchart].

3.122 An application presenting several classifications for its independent claims does not necessarily indicate a lack of unity of invention. A practical and broad-ranging analysis must be conducted of the level of inter-dependence among the inventions presented, compared to the state of the art disclosed by the search report.

**Intermediate and End Products**

3.123 The status of unity of invention must be deemed to be present within the context of intermediate and end products, where:

i. the intermediate and end products have the same essential structural elements, meaning that their basic chemical structures are the same or their chemical structures are closely inter-related in technical terms, with the intermediate product including a structural element that is essential in the end product; and
ii. the intermediate and end products are technically inter-related, meaning that the end product is produced directly from the intermediate product or is separated therefrom by a small number of intermediate products, all containing the same essential structural element.

3.124 Unity of invention may also be present among intermediate and end products whose structures are not known, between an intermediate product with a known structure and an end product with an unknown structure, or between an intermediate product with an unknown structure and an end product with an unknown structure, mentioned as examples. In these cases, there must be sufficient evidence to conclude that the intermediate and end products are closely inter-related in technical terms, when the intermediate product contains the same essential element as the end product or embodies an essential element in the end product, mentioned as examples.
Different intermediate products used in different processes for the preparation of the end product may be claimed, provided that they have the same essential structural element. Intermediate and end products may not be separated in the process leading from one to the other, by an intermediate product that is not new, which represents the special technical characteristic conferring unity of invention on the intermediate and end products. When different intermediate products for different structural parts of the end product are claimed, unity is not present among the intermediate products. If the intermediate and end products are families of compounds, each intermediate compound must correspond to a compound claimed in the end products family. However, some end products may not have a compound corresponding to the intermediate product family, meaning that these two families need not be completely congruent.

The simple fact that, in addition to the capability of being used to produce end products, the intermediate products also present other possible effects or properties may not adversely affect the unity of the invention.

Intermediate products are illustrated in the following examples:

**Example 1:** Claim 1: New product with structure A - intermediate compound
Claim 2: Product prepared through the reaction between the intermediate compound with structure A and a compound X - end product

**Example 2:** Claim 1: Product of the reaction between A and B - intermediate
Claim 2: Product prepared through the reaction between the intermediate compound and substances X and Y - end product

For the types indicated in examples 1 and 2, the chemical structures of the intermediate and/or end products are not known. In example 1, the structure of the product addressed by Claim 2 – end product – is not known. In example 2, the structures of the products addressed by Claim 1 – intermediate and Claim 2 – end product – are unknown.

There is unity of invention if there is evidence leading to the conclusion that the characteristic of the end product that is an inventive characteristic, depending on the characteristics of the intermediate product, if the purpose of using the intermediate products in the types shown in examples 1 and 2 is to modify certain properties of the end product. The evidence may lie in the data presented in the specification, showing the effects of the intermediate product on the end product. If there is no such evidence, then there is no unity of invention based on the relationship between the intermediate and end products.

**Alternatives (“Markush Groupings”)**

When a Markush grouping addresses alternatives for chemical compounds, they will be considered as being similar in nature, provided that the following criteria are met:

i. all the alternatives have a property or activity in common; and
ii. there is a common structure, meaning that a significant structural element is shared by all the alternatives or, in cases where the common structure cannot be the only criterion for establishing the unity of the invention, all the alternatives belonging to an acknowledged class of chemical compounds at the state of the art, to which the invention belongs.
3.131 Verifying whether a group of inventions is interconnected in a manner that constitutes a single general inventive concept must be conducted separately if the inventions are addressed by separate claims or through the alternatives presented in a single claim.

3.132 Alternative forms of an invention may be claimed through a plurality of independent claims, as indicated in item 3.108, or in a single claim. An independent or dependent claim may address alternatives, provided that the number and presentation of the alternatives in a single claim does not make it obscure or hard to understand, and provided that the claim presents unity of invention, for example: a motor characterized by gearing A fabricated with material X or Y or Z. For a single claim, the presence of two alternatives as independent forms may not be immediately evident. However, in both cases, the same criteria must be deployed in order to decide whether or not there is unity of invention, and the lack of unity of invention may also exist within a single claim.

**INDIVIDUAL CHARACTERISTICS IN A CLAIM**

3.133 Unity of invention is present in a claim that consists of a combination of individual characteristics, where these characteristics present a technical inter-relationship.

3.134 In cases where this technical inter-relationship does not exist, but what occurs is a mere juxtaposition of elements, there are no grounds for alleging a lack of unity for the invention.

**DEPENDENT CLAIMS**

3.135 No objection raised over a lack of unity of invention a priori is justifiable for a dependent claim, based on the general concept that what they have in common is the object of the independent claim, which is also contained in the dependent claim.

**Example:** Assume that Claim 1 addresses a turbine rotor blade in a specified manner, while Claim 2 addresses a “turbine rotor blade as described in Claim 1, comprised of alloy Z.”. The special technical characteristics linking the dependent claim to the independent claim for the turbine rotor is the “turbine rotor blade shaped in a specific manner.”

3.136 When an independent claim is not patentable, the unity of invention among its dependent claims must be given careful consideration. The other remaining dependent claims must be assessed to see whether they present the “special technical characteristics” required to endow the claim chart with unity of invention.

**DIVISIONAL APPLICATION ANALYSIS**

3.137 For the purposes of article 26 of the Brazilian IP Statute, the “original application” is deemed to be the first application filed, which may be divided only through to the end of the initial examination. Further divisional applications that have already been divided will not be accepted. Decisions must be taken simultaneously on the original application and its divisionals.

3.138 The issue related to the analysis of the claims, as well as the patentability requirements, breaching article 32 of the Brazilian IP Statute by extending the scope addressed in the original application, and seeking dual protection, is a matter that must be explored in the substantive examination, meaning after the divisional application notification is published in the Brazilian IP Statute Official Gazette under dispatch code 2.4.
3.139 Furthermore, during the substantive examination of the divisional application, with notification under dispatch code 2.4 published in the BRPTO Official Gazette, the Examiner must analyze item II of article 26 of the Brazilian IP Statute, verifying whether the matter addressed by the divisional application exceeds that disclosed in the original application. Having complied with this criterion, the examination will continue. Otherwise, the divisional application will be dismissed, through an announcement published under dispatch code 11.12 in the Brazilian IP Statute Official Gazette, indicating the reasons why it was dismissed. Should the matter addressed by the application exceed the matter disclosed in the original application, the Examiner must indicate one or more segments where the added matter was noted.

3.140 As stipulated in item 6.1 of Rule #127/97: “The patent application may be divided into two or more applications up to the end of the examination:

a. At the request of the applicant, even when the application presents a group of inventions that are inter-related through the same inventive concept; (Wording to be added to the version in effect of Rule #127/97);

b. Pursuant to the examination opinion, when the technical examination shows that the application contains a group of inventions that comprise more than one inventive concept or more than one utility model. (Wording to be added to the version in effect of Rule #127/97)

3.141 Should a divisional application be generated from a matter that has already been examined and did not present the merit needed for patentability, this must be rejected, with the same objections remaining valid on such merit.

**Unity of Invention and Dual Protection**

3.142 The procedure for dividing a patent application must consist of the removal of part of the matter claimed presented in the original application, in order to constitute the divisional application(s). Merely replicating part of the matter claimed in the original application in order to constitute a divisional application, in fact, results in a multiplication of the application, rather than a division.

3.143 During the substantive examination of the divisional application, should there be any increase in the scope claimed, compared to the original application, the examiner must issue an examination opinion based on article 32 of the Brazilian IP Statute, as alterations to the claim chart may be introduced only through to the time of the examination of the original application.

3.144 In its item 6.1.1., Rule #127/97 stipulates that divisional applications may not imply dual protection for the invention or utility model. Article 6 of the Brazilian IP Statute states that the author of an invention or utility model will be assured the right to obtain the patent assuring ownership there of. For a better understanding of this Article, two patents may not be awarded for a single invention or utility model.

3.145 The existence of dual protection in a divisional application must be analyzed through comparing its claim chart with the claim chart in the original application, and with the claim charts in the other divisional applications, if any. In this case, the divisional application must be rejected, for failing to comply with the provisions set forth in article 6 of the Brazilian IP Statute.

3.146 Should a divisional application address a matter more specific than that covered by the original application from which it derives, the technical examination of this divisional application must be rejected for failure to comply
with the provisions set forth in article 6 of the Brazilian IP Statute, as this implies dual protection, because the broader matter addressed in the original application already encompasses the more detailed matter is addressed in the divisional application.

3.147 A claim considered to constitute an alternative implementation of the invention and included in the claim chart presented in the original application may be withdrawn from the original application and addressed by a divisional application, at the decision of the applicant, even if such claim falls within the scope of the inventive concept claimed in the original application.

**Chapter IV. Drawings**

4.01 Should drawings be presented, they must be listed in the specification, by specifying their graphic representations, such as: views, cross-sections, perspectives and electric circuit diagrams. When the specification mentions an element in the drawing(s), such element must be accompanied by its reference sign in brackets, such as: “the hose (4) is connected to the valve (10).”

4.02 It is noted that the terminology and the symbols must be uniform throughout the entire application.

4.03 If the quality of the drawings presented is not good enough for proper visualization, the Examiner must issue a request, under article 24 of the Brazilian IP Statute and with attention to article 32 of the Brazilian IP Statute.

4.04 The drawings must preferably comply with the matters established in the Brazilian standards for technical drawings. Along these lines, the Examiner may issue a requirement, in the case of drawings prepared by hand, for example.

4.05 The presentation of reproductions of photographs instead of figures will be accepted only in cases when this is the only possible way of graphically representing the object addressed by the applications, such as metallographic structures, and provided that such reproductions are clear enough to allow the visualization of all the details of the object.

4.06 Color photographs are accepted only when this is the sole possible way of graphically representing the object addressed by the application. Should the quality of the presented photographs not be good enough for proper visualization, the Examiner may not issue a request for the presentation of better quality photographs, due to the risk of adding matter. The material initially presented must be accepted for examination.

**Chapter V. Abstract**

5.01 As many databases are used, consulting only summaries and titles, the abstract must contain key words for easy retrieval. This is due to the need for the correct dissemination of the technology encompassed by the invention to society as a whole.

5.02 Furthermore, bearing in mind that users consult the contents of the abstract in order to decide whether to read the document in full, this must provide a concise description with an indication of the technical field of the invention, a technical explanation of the invention as such, and possibly also its main application.
Appendix I

Unity of Invention Analysis Processing Flowchart

1. Is there unity of invention before conducting the search?
   - Yes
     - Search for the Special Technical Characteristic
     - The Special Technical Characteristic is known
     - The Special Technical Characteristic is not known

2. The Special Technical Characteristic is known
   - Yes
     - Examination of the claim chart
   - No
     - Supplement the search for the entire QR

3. The Special Technical Characteristic is not known
   - Yes
     - Examination of the claim chart
   - No
     - Supplement the search for the entire QR

4. Did the search encompass the entire claim chart?
   - Yes
     - Examination of the claim chart
   - No
     - Supplement the search for the entire QR

5. State that there is no unity of invention (article 22). State that the Special Technical Characteristic is known

6. State that there is no unity of invention (article 22); search and examination of the first claimed unity of invention
APPENDIX II

MODIFICATIONS TO RULE #127/97

6. DIVISIONAL APPLICATIONS

6.1 The patent application may be divided into two or more segments through to the end of the examination:

a. By an applicant request, even when the application presents a group of inventions that are inter-related through the same inventive concept; (Wording to be added to the version in effect of Rule #127/97)
b. Pursuant to an examination opinion, when the technical examination shows that the application contains a group of inventions that comprise more than one inventive concept or more than one utility model; (Wording to be added to the version in effect of Rule #127/97)

7.5 End of Examination – For the purposes of articles 26 and 31 of the Brazilian IP Statute, the end of the initial stage of the examination is deemed to occur on the date of the conclusive examination opinion on patentability, or the 30th day prior to the publication of the decision on the approval, rejection or definitive dismissing of the application, whichever occurs later. (Wording to be added to the version in effect of Rule #127/97)

15.1.3.2 WORDING OF CLAIMS

a. Claims must begin with the title or the part of the title corresponding to the respective category, and may contain the phrase “characterized by” once only; (Wording to be added to the version in effect of Rule #127/97)
b. Each claim must clearly and precisely define in a positive manner the technical characteristics to be protected thereby; (Wording to be added to the version in effect of Rule #127/97)
c. With regard to the characteristics of the invention, claims may not contain references to the specification or the drawings such as “as described in part… of the specification” or “as represented by the drawings”; (Wording to be added to the version in effect of Rule #127/97)
d. Claims will not be accepted with explanatory segments addressing the functioning, advantages and simple use of the object; (Wording to be added to the version in effect of Rule #127/97)

15.1.3.2.1 INDEPENDENT CLAIMS

a. Such claims are intended to protect the specific technical characteristics that are essential to the invention as a whole, with each category of claim having the right to at least one independent claim; (Wording to be added to the version in effect of Rule #127/97)
b. Independent claims in different categories that are linked together by the same inventive concept, in which one of the categories is especially adapted to another must be worded in a manner that clearly shows such interconnection, using phrases in the initial part of the claim such as, for example: “device for performing the process defined in claim…”; “Process for obtaining the product defined in claim…”; (Wording to be added to the version in effect of Rule #127/97)
c. Independent claims may serve as the basis for one or more dependent claims, being grouped in the order corresponding to the title of the application. (Wording to be added to the version in effect of Rule #127/97)
**15.1.3.2.2 Dependent Claims**

a. With unity of invention maintained, these are claims that include all the characteristics of other prior claim(s) and define the details of such characteristics and/or additional characteristics that are not deemed to constitute essential characteristics of the invention, necessarily containing an indication of the dependence of such claim(s) and the expression “characterized by”; (Wording to be added to the version in effect of Rule #127/97)

b. The relationships of dependence must be defined precisely and comprehensively for dependent claims, not accepting wording such as “pursuant to one or more of the claims…,” “pursuant to the preceding claims…,” “pursuant to any of the prior claims,” or similar. Wording such as “pursuant to any one of the prior claims” and “pursuant to one of the prior claims” is accepted; (Wording to be added to the version in effect of Rule #127/97)

c. Any dependent claim addressing more than one claim (multiple dependence claim) must refer to these claims in an alternative or cumulative manner (worded as additions), with only one of the wordings – either alternative or cumulative – being permitted for all multiple dependence claims, provided that the relationships of dependence of the claims are structured in a manner that allows an immediate understanding of the possible combinations resulting from such dependences; (Wording to be added to the version in effect of Rule #127/97)

d. Whether alternative or cumulative, multiple dependence claims may serve as the basis for any other multiple dependence claim, provided that the relationships of dependence of the claims are structured in a manner that allows an immediate understanding of the possible combinations resulting from these dependences. (Wording to be added to the version in effect of Rule #127/97)

e. All dependent claims referring to one or more prior claims must be grouped in a manner that ensures a concise structure for the claim chart. (Wording to be added to the version in effect of Rule #127/97)

**15.3.2.1** Units of weight and measurement must be expressed through the International System of Units, their multiples and sub-multiples, except for terms established in specific technical areas, such as; Btu, mesh, barrel, inches. (Wording to be added to the version in effect of Rule #127/97)
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.
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

51. 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.

Example: 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 accordance 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 of 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.

SIX. 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

§1. 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.

Example²: 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 data 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.
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.

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.

### §1. Assignment of Publication Date

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

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.

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.

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.

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.

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:


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.

**Example**: 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”.

**Example**: A claim of food composition consisting of a dairy product is not new given a prior 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.

**Example**: 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.

**Example**: 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.

**Example**: 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 125ºC and 130ºC. The state of the art discloses the same process for obtaining the product, using temperatures of 120ºC to 180ºC, with tests presented using temperatures of 140ºC and 150ºC. 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 125ºC and 140ºC. The state of the art discloses the same process to obtain the product, using temperatures of 120ºC to 160ºC, with tests presented using temperatures of 140ºC and 150ºC. In the latter case, the claimed process includes a temperature that was explicitly disclosed and consolidated in the state of the art (140ºC), 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 1, 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. OveRveW

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 aesthetic. 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.

OBSOVIUS 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-OBSVIOUS 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.

O B V I O U S  S E L E C T I O N

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 130oC, with illustrative examples using temperatures of 110oC and 125oC. It is now determined that in the temperature range of between 63ºC and 65ºC, 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.
Example: 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.

§1. 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:

![Markush Formula Diagram](image)

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

§II. 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 it is 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.
Examination Guidelines for Patent Applications

Computer-implemented Inventions


Upon publication, this text will be part of the Patent Application Examination Guidelines setting out the current understanding of the BRPTO on examination of computer-implemented inventions. Other inherent exam topics are listed and discussed in the general guidelines.
1. **Introduction**

The purpose of this document is to present the Patent Application Examination Guideline adopted by the BRPTO for steering the technical examination of patent applications addressing computer-implemented inventions, in compliance with the Brazilian IP Statute (Statute #9,279/96) as well as the procedures contained in Rule #127/97.

A Patent Application addressing computer-implemented inventions, being based on a process, is encompassed only by the nature of the patents of invention. Pursuant to Article 9 of the Brazilian IP Statute, a Utility Model Patent Application must refer to “an object of practical use that presents a new form or arrangement…”, which is not the case for computer-implemented inventions.

Like any application for a patent of invention, applications involving computer-implemented creations must comply with the legal requirements, more specifically, those addressed in the Brazilian IP Statute, notably: novelty, inventive step and industrial application.

2. **What is deemed to constitute an invention**

In its Article 10, the Brazilian IP Statute does not consider the following matters to constitute inventions or Utility Models: “discoveries, scientific theories and mathematical models; purely abstract concepts; commercial or business schemes, plans, principles and methods of accounting, financial, publishing, lottery or fiscal nature; literary, architectural, artistic and scientific works or any aesthetic creation; computer programs per se; presentation of information; rules of a game; operating or surgical techniques and methods; as well as therapeutic or diagnostic methods for application in the human or animal body, as well as 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”.

A creation is deemed to constitute an invention when the resources used to solve the problem being addressed are not found in a field included in the items listed in Article 10 of the Brazilian IP Statute. Pursuant to Rule #127/97, the invention must be included in a technical sector (item 15.1.2 c) solve technical problems, offering a solution to such problems (item 15.1.2 e) and have a technical effect (item 15 1.2 f). The application must thus clearly prove the technical nature of the problem to be solved, the proposed solution and the effects attained. It must be stressed that, in order to assess the incidence of the claimed matter under Article 10 of the Brazilian IP Statute, the claims must be considered as a whole. For example, a method identifying banknotes through the patterns of their images, colors and texts may well be patentable, as this addresses pattern recognition techniques. In this case, despite the mention of banknotes and its application in the banking network, the method does not fall under item III of Article 10 of the Brazilian IP Statute.

For a Patent Application presenting an computer-implemented invention, the framing of the object of the patent application under the exceptions set forth in the items listed in Article 10, regardless of whether the claim category involves a defined process or product merely through its functionality. For the purposes of analyzing a process implemented through a computer program, it is irrelevant whether this process is run on a computer for general use (personal computer) or for specific use (PIC, FPGA, etc.).

The following items will analyze cases subject to the requirements listed in Article 10 that may involve computer-implemented.
2.1 Computer Program per se

The computer program per se addressed by item V of Article 10 of the Brazilian IP Statute refers to the literal elements of the creation, such as the source code, understood as an organized set of instructions written in natural or coded language. The computer program per se is not deemed to constitute an invention and is consequently not open to protection under patent, as it is a mere expression of a technical solution, being intrinsically dependent on the programming language.

A set of instructions in a language, an object code, a source code or a source code structure, even if creative, is not deemed to constitute an invention, even if it provides technical effects. For example, alterations to the source code of the program that endow it with the benefit of faster speed, smaller size (of either the source code or the space occupied in memory), modularity, etc, belong to the field of the computer program per se, despite being technical effects. In terms of objects open to copyright, the computer program is not deemed to constitute an invention and is consequently excluded from patentability.

However, an industrial computer-implemented creation (process or product associated with the process) that solves a problem found in the state of the art and attains a technical effect that is not related only to the manner in which this computer program is written, might be deemed to constitute an invention.

When assessing the technical effect, consideration is given to whether the effects attained through all the steps followed by the computer-implemented invention. Examples of technical effects attained by computer-implemented inventions are: optimization (of run times, hardware resources, memory use, and database access), fine-tuning the user interface (not merely for aesthetics), file management, data switching and others. It is important to stress that, should the technical effects arise from alterations to the computer program code, rather than the method, the creation is not deemed to constitute an invention.

It must be stressed that creations falling under other items listed in Article 10, whether or not they are implemented by computer programs, are not deemed to constitute inventions. For example, a mathematical method implemented by a computer program is not deemed to constitute an invention, not because it is implemented by a computer program, but rather because it is a mathematical method, falling under item I, Article 10 of the Brazilian IP Statute.

Mere interaction between the computer program and the hardware (for example: conventional access to memory, busbars, input and output devices) does not guarantee that the creation implemented by such a program shall be deemed an invention. It is necessary to discern a technical effect beyond this interaction, as the technical effect of an invention must necessarily be intentional and directly controlled by the proposed invention, regardless of whether such technical effect takes place inside or outside the processing unit. Therefore, inventions that, for example, are intended to cause a reduction in memory access time, a better control of a robot’s element or a better coding of a radio signal received, satisfy the technical effect criterion even when internal to the computer, because there is a direct causal relationship between the invention and such effects in these cases.

Although modifications in the manner in which the computer program is written may give rise to indirect physical effects, such as variations in electric current, this is not sufficient to confer a technical character on a computer-implemented creation.

Item V of Article 10 of the Brazilian IP Statute, when mentioning that “the computer program per se” is not deemed
to constitute an invention, merely separates and distinguishes the protection systems when addressing an 
invention that might involve computer programs. In other words, a computer program may form part of the process 
that attains a technical effect, which thus means that there are two objects to be protected: the copyright for the 
computer program and the patent’s rights for the processes solving technical problems, attaining a technical effect 
unrelated to alterations in the code.

2.2 MATHEMATICAL METHODS

A method solving a problem that is exclusively mathematical (for example, deductions, operations, mathematical 
equations) is not deemed to constitute an invention, as it addresses a matter excluded by item I of Article 10 of the 
Brazilian IP Statute. The fact that the mathematical method is implemented by a computer program is irrelevant for 
the framing of such method under item I of Article 10 of the Brazilian IP Statute.

On the other hand, in order for a method implemented by a computer program involving mathematical concepts to 
be deemed to constitute an invention, such method must be intrinsically linked to an application with a practical 
technical nature. Thus, a process involving a mathematical concept is not immediately a matter excluded by item I 
of Article 10 of the Brazilian IP Statute. During the examination of the claimed object, should this process deploy the 
mathematical concept in order to obtain a technical solution to a technical problem, such process might be deemed 
to constitute an invention, provided that the resulting effects are technical rather than purely mathematical.

For example, a specific numerical integration method is not deemed to constitute an invention as its outcomes 
are purely mathematical, which is the integration operation, consequently, not being open to patent protection. 
However, a motor control system that uses this numerical integration technique in a manner that results in faster 
operating speed or better stability, might be deemed to constitute an invention, as it is applied to a technical 
problem, produces a technical effect and consequently is not classified as a mathematical method. In this case, the 
numerical integration technique is not protected, and remains in the public domain, open to use in other solutions 
to different technical problems.

Creations involving mathematical concepts may be deemed to constitute inventions when applied to practical 
technical problems and dealing with information associated with physical magnitudes or abstract data. The seismic 
data filtering method that allows for noise reduction, the image processing method that compacts the data or 
generate special effects such as zooms, a method that implements a control resulting in a substantial upgrade 
in the dynamic behavior of a specific vehicle or robot, constitute examples of methods dealing with information 
associated with physical magnitudes, respectively: seismic data, image data and movement sensor measurements.

Methods involving encryption or data compacting may also be deemed to constitute inventions, even if referring 
to abstract data, when addressing technical problems such as data security and optimization of hardware 
resources, and not specifically the mathematical method. Thus, an encryption method using abstract data in a 
specific manner, and whose outcome is a virtual product (data protected by a security key) might be deemed to 
constitute an invention, as it solves a problem of ensuring the security of information transmitted through 
a communications channel.

2.3 COMMERCIAL, ACCOUNTING, FINANCIAL, EDUCATIONAL, PUBLISHING, LOTTERY OR FISCAL NATURE METHODS

In general, a commercial, accounting, financial, educational, publishing, lottery or fiscal nature method might
be implemented by a computer program. However, item III of Article 10 of the Brazilian IP Statute stipulates that schemes, plans, principles or methods that are commercial, accounting, financial, educational, publishing, lottery or fiscal nature related are not deemed to constitute inventions. The fact that this method is implemented by a computer program is irrelevant for the framing of such method under item III of Article 10 of the Brazilian IP Statute. Examples of creations that fall under item III of Article 10 of the Brazilian IP Statute include: business feasibility analyses, market analyses, auctions, consortia, incentive programs, point of sale methods (POS), fund transfers, banking methods, tax processing, insurance, patrimony analyses, financial analyses, auditing methods, investment planning, retirement plans, medical aid schemes, on-line purchase methods, air ticket sales methods over the Internet, among others.

Should the matter claimed be a method presenting financial, accounting, educational, publishing, lottery or fiscal nature stages, then this method will fall under item III of Article 10, not being deemed to constitute an invention. For example, an international fund transfer method (through a banking network or E-cash) whose functional steps include foreign-exchange and service fee calculations is not deemed to constitute an invention, as the financial steps of this method are so intrinsically linked to the object that it would not be possible to imagine its existence separately therefrom. However, when some of the steps of the process fall under item III of Article 10 of the Brazilian IP Statute, it might be deemed to constitute an invention, provided that these steps are removed and the remaining matters can be applied in a technical field, producing technical effects.

An operating method for an automatic teller machine characterized by the stages of reading the user bankcard, identification and comparison of the password with the information on the card, provide a technical, non-financial solution for confirming the identity of the user. Thus, this method might be deemed to constitute an invention. Other solutions related to communication protocols, encryption applied to bank accounts or data format conversion may also be deemed to constitute inventions. On the other hand, the operating steps of an automatic teller machine, for the financial part of the method, such as the fund transfer method or the balance checking method, are not deemed to constitute inventions.

### 2.4 Therapeutic or Diagnostic Methods for Application in Human or Animal Bodies

Method in which one of the described steps addresses a therapeutic or diagnostic procedure for application in human or animal bodies are not deemed to constitute inventions (item VIII, Article 10 of the Brazilian IP Statute).

A method for processing electrocardiograph signals that optimizes the calculation of non-stationary signals, allowing parameters to be obtained that may assist the physician in diagnosing the pathology, might be deemed to constitute an invention, as this method is not conclusive in terms of the outcome of the diagnosis, and might also not be considered as applied in human or animal bodies. Should the proposed method reach a conclusion on the diagnosis of the disease, but have no steps describing its application in human or animal bodies, it may be deemed to constitute an invention.

### 2.5 Presentation of Information

Any computer-implemented creation comprised solely of its information content, such as music, text or images, is deemed to constitute the presentation of information. Consequently, it falls under item VI of Article 10 of the Brazilian IP Statute. However, creations presenting technical functionality that are not mere presentations of information may be deemed to constitute inventions. The method associated with the functional aspects of a user
interface that provides technical effects might be deemed to constitute an invention. For example, a mechanism that combines the number of mouse clicks with the selection of a specific on-screen object.

The matter addressed in the claim that defines a graphic interface where the icons are presented on the upper screen with a roll-bar on the right side, with no functionality, is deemed to constitute the presentation of information. On the other hand, a claim addressing a graphic interface associating personal annotations with segments of an electronic document through XML tags may constitute a technical solution that is open to patentability.

When a creation that generates coded information has a technical character, it might be deemed to constitute an invention. Moreover, if the encoded information has a functional and structural relationship to a recording medium, process or device, these can also be deemed to be considered invention. This is because the claimed object refers to the support, the process or the device presenting information, and not just to the presentation of the information. A data recording process with specific coding on a support (HD, CD, DVD, etc) or a recording process using volumetric support characteristics, thus enhancing the storage capacity, or a recording device (recorder) using these processes might be deemed to constitute inventions. However, a support comprised only of its information content falls under item VI of Article 10 of the Brazilian IP Statute. Other information on claims involving recording support is found in section 6.4.

3. Process Classes for Computer-Implemented Inventions

As set forth in the previous Section, it is concluded that there are three classes of processes related to computer-implemented inventions. It must be stressed that, like any invention, the processes listed below must comply with the Brazilian IP Statute (Statute #9,279/96) in order to be patentable, as well as Rule #127/97, achieving a technical effect and solving a technical problem that dismisses the possibility of awarding patents to purely abstract creations.

i. Process using physical magnitudes to generate a physical effect or product

This class encompasses processes that work with physical magnitudes in order to attain the transformation or reduction of a product to a different state, or result in a new product. The fact that a process belongs to this class is an indication that this computer-implemented creation might be deemed to constitute an invention.

Examples: temperature control of a kiln or furnace to transform a product; stabilization of the dynamic behavior of a vehicle during a pre-set course; an automatic transmission system in vehicles; print control; industrial machine control;

ii. Process using physical magnitudes to generate a virtual product:

This class encompasses processes working with physical magnitudes converted into digital signals, in order to transform these signals into a product stored on a device.

Examples: the processing of data, representing physical characteristics (size, color, delay) generating a virtual product (video, music, image), image and audio treatment involving the physical magnitudes of amplitude and phase delay;

iii. Process using abstract magnitudes to generate a virtual product:
The processes included in this class work with abstract magnitudes, created within the process environment without representing physical magnitudes, in order to transform a virtual product into another virtual product stored on a device.

Examples: data compression, encryption, database management, data communication protocols.

4. Algorithm, On-board Software and Text Processors

The concepts of algorithms, on-board software and text processors are found recurrently in applications involving computer-implemented creations, and may prompt doubts regarding the framing of the creation under the items set forth in Article 10 of the Brazilian IP Statute.

Algorithm

An algorithm is deemed to be a sequence of logical steps to be followed for solving a specific problem. According to this definition, an algorithm consists of a method or process, and must consequently be claimed as such. In order to constitute an invention, this method or process may not fall under the items set forth in Article 10.

For example, an algorithm (claimed as a method) that stabilizes the movement of a robot arm through control techniques is intended to solve a technical problem, producing a technical effect, and is deemed to constitute an invention. However, an algorithm that is intended to merely solve a mathematical function is deemed a mathematical method, and is consequently not deemed to constitute an invention, as it falls under Article 10 of the Brazilian IP Statute.

On-board Software

The concept of on-board software that has been adopted addresses a computer program that controls the behavior of a dedicated device. In this context, both the functionality associated with the behavior of this device might be patented as a process (provided that this process is deemed to constitute an invention), just as the dedicated device might be patented in the form of a product. However, the computer program is not patentable, as it is not deemed to constitute an invention.

The fact that a creation is onboard does not constitute a definitive criterion for its exclusion from Article 10 of the Brazilian IP Statute, as a method associated with the behavior of the device may not be deemed to constitute an invention. However, if the contribution to the state of the art is encompassed by the structural characteristics (rather than in the functional aspects) of the dedicated device, it might be open to patentability, even if the method is not deemed to constitute an invention.

Text Processors and Processing

Text processors are deemed to consist of the software or computer program used to edit texts. As a computer program, text processors are not deemed to constitute inventions as they fall under item V of Article 10 of the Brazilian IP Statute.

On the other hand, text processing is deemed to constitute a process applied to a text, and might be deemed
to constitute an invention, similar to an audio or video processing method. For example, a text compression method that uses statistical information to represent the text in a more efficient manner is deemed to constitute an invention. However, the text correction method, even if claimed as a set of linguistic rules, is not deemed to constitute an invention under item II, Article 10 of the Brazilian IP Statute, as it constitutes a purely abstract concept related to the construction of the language as such.

Text processing methods that introduce technical effects implemented through text processors may be deemed to constitute inventions. For example, a word search method in a text processor using indexes, following a specific methodology that can provide faster and more efficacious results, might be deemed to constitute an invention.

5. Patentability Criteria

5.1 Novelty

For the purposes of examining the novelty of applications for patents of computer-implemented invention, the same rules are applied as for the examination of novelty in any patent of invention.

5.2 Inventive Step

Pursuant to Article 13 of the Brazilian IP Statute, “the invention shall be taken to involve inventive step when, for a person skilled in the art, it does not derive in an evident or obvious manner from the state-of-the-art”.

The fact that the invention is solving new technical problems and attaining new functionalities is an indication of inventive step. Even when the technical problem is not new, it is nevertheless possible that inventive step may be present. An computer-implemented invention for a product/process formerly run by specific hardware does not present inventive step, when the outcomes are merely equivalent.

Furthermore, the mere automation of an existing manual method (that involves only human agents) by an computer-implemented invention is also not endowed with inventive step. Mere automation is understood as a direct link between the manual and automated method.

A method is deemed to be known at the state of the art when comprised of blending compound X with compound Y. An application claiming an inventive industrial robot consisting of gears A, B, and C, which allows this process to be automated might be patented. Furthermore, the functioning method on the robot and the manner in which the elements that constitute the robot must interact in order to implements this blend might be protected, provided that it is deemed inventive. In this case, the protection conferred on this method addresses the operationality of this robot, rather than the blending method known at the state of the art. Consequently, this does not constitute protection for mere automation, but is instead deemed to be inventive compared to the state of the art. However, a claim for a “method implemented by a robot characterized by blending compound X with compound Y” might not be protected, as the claimed method is not deemed to be inventive, as it constitutes the mere automation of a method that is already known.

For a CAD program that, based on a list of electronic components, defines the best route for conduction wires on a printed circuit board that carries a desired electronic circuit, a claim addressing the routing method for these paths based on the component hierarchy and optimizing the path constitutes a matter open to patent. The patent
awarded must thus refer to the functionality attained by the hardware assembly and process implemented by a computer program that is responsible for the technical effect attained, rather than a computer program, even if all the hardware described is already found at the state of the art.

For the purposes of inventive step, technical effects intrinsic to the computer-implemented invention must be taken into account. Indirect technical effects are attributes of the computer system, rather than of the invention. Some of the technical effects attained are more the outcome of the qualities of the computer used rather than resulting from the invention, particularly with regard to processing speed, capacity to process large quantities of data and the uniformity and accuracy of the results. Thus, it is necessary to distinguish the technical effects achieved by the invention from the legacy technical effects handed down by the computer system used.

5.3 **Industrial application**

Computer-implemented inventions may be claimed as methods and / or products. The fact that a method is implemented by a computer program does not undermine the possibility of its industrial application. Consequently, the same rules are applied to the examination of an industrial application for any patent of invention.

6. **Structure of a Patent Application for an Computer-implemented Invention**

6.1 **Title**

The title must be concise, clear and accurate, identifying the object of the application and listing the categories of the claims presented. Expressions or words such as: software, computer program, method of doing business, therapeutic method, and financial method, which fall directly under the constraints set forth in Article 10 of the Brazilian IP Statute are not accepted.

6.2 **Specification**

The description of the invention must be clear and sufficient, whereby a person skilled in the art could reproduce the invention. Small portions of the source code may be presented, if deemed useful for understanding the invention.

It is of fundamental importance that the state of the art deemed relevant is described, highlighting the technical problems in a clear and accurate manner. Next, the objectives of the invention must be defined and the solution proposed for such problems, or limitations for which no solution has yet been found, must be necessarily set forth in a clear, convincing and detailed manner.

Except when a respected technical term in Portuguese is found in common use among persons skilled in the art, technical terms or abbreviations in a foreign language should not be translated. Thus, terms that are usual at the state-of-the-art, such as, for example: bitmap, boot, buffer, byte, cache, CDMA, default, desktop, dial-up, drivers, firewall, host, HTML, login, hub, mouse, online, pixel, plug-in, prompt, QPSK, RAM, among others, must not be translated. Once such words develop the corresponding terms in Portuguese that are commonly used at the state-of-the-art, they are preferred. Other terms already in common use must be used in Portuguese, such as browser (navegador), bus (barramento), device (dispositivo), database (banco de dados), floppy disk (disquete), hard disk (disco rígido), multimedia (multimídia), network (rede), password (senha), router (roteador) and switch (comutador), among others.
6.3 Drawings

Drawings are optional, although, if applicable, an computer-implemented invention may be described in its main blocks in terms of their functionalities, meaning the flowchart of inventive steps of the method implemented by computer programs must be presented through key words and/or brief sentences presenting these functionalities, such as for example: “Has the user inserted the card?” For a better understanding of the invention, drawings must thus be presented that provide a general overview of the system in physical terms, with flowchart describing its main functionalities and data structures and, should the invention involve a user interface, some of the main presentation screens.

6.4 Claims

For computer-implemented inventions, claims may be presented for processes (method) or products (system, device or equipment associated with the process), necessarily indicating clearly the type of claim in question.

A process claim must address a set of actions and consequently may not contain the expression “means to” when such expression may be construed as a “device for”. A product claim must address the technical means used, and not a set of actions. Otherwise, both claims will lack clarity in terms of the claim category.

It must be stressed that the expression “means to” does not necessarily result in a lack of clarity and poor definition due to the simple fact that it is included in a process claim (method). For example, an independent process claim addressing a “wireless data transmission method” may contain among various sub-stages “A, B, C, D, etc.” a sub-stage “B” in which “the data are shared through a Code Division Multiple Access (CDMA) network that includes the means to compress data using symmetrical arithmetic coding algorithms;”, with a simple fact of this sub-stage containing the expression “means to” does not automatically result in the claim being undefined or not clear, as a person skilled in the art might easily discern that the matter for which protection is requested is limited to the use of the “means” handling the data compression.

Claims may not contain segments of source code, in order to avoid problems caused by doubtful interpretation under item V of Article 10 of the Brazilian IP Statute. Computer program claims are not accepted, as this wording falls directly under item V of Article 10 of the Brazilian IP Statute.

Claims involving matters addressed by Article 10 are not deemed to fall under this Article merely because they describe that the function or desired outcome is achieved by the use of, for example, a computer or a computer component (such as a processor) or through the Internet.

Some claims do not described a solution of the problem, but instead describe the problem itself. Such wording should not be included in the claim Chart, as the protection must address the proposed solution, rather than the problem presented.

6.4.1 Process Claims

Process claims must be written as a sequence of steps, describing the functionalities attained. For example: “method for the automatic control of gears characterized by the steps of measuring the engine speed, generating a slip reference signal, comparing the engine speed and the entry speed, controlling the gear action”. Such claims must be worded as a method or process, as both refer to a set of steps for attaining a technical outcome.
6.4.2 Product Claims

Product claims must be written in terms of their physical elements (devices, memory etc.) or in terms of means plus functions. "Means plus functions" are considered as expressions in which the construction contains means (modes) or devices for performing such functions, without defining the specific technical characteristics thereof. For example, “means for coding”, “device for coding”, “coder for coding”. It must be stressed that a product claim must always refer to its physical elements, and not just to its functions. In cases where the invention refers to different items of equipment working together, the invention must be defined in a system claim, clearly explaining the relationship between such items of equipment and their functions.

A device associated with a computer-implemented creation is not patentable, when defined in the form of means plus functions, in which the entire contribution comes from an aspect addressed by any item of Article 10 of the Brazilian IP Statute. Thus, a device for calculating the solution to a differential equation comprised only of the means for performing the fourth order Runge Kutta method is not endowed with patentability as its contribution lies in the mathematical method, which is encompassed by item I of Article 10 of the Brazilian IP Statute. A device that merely handles the numerical implementation of a breakdown of a specific function through the use of Transformed Wavelet is similarly not endowed with patentability, also addressed by Article 10 of the Brazilian IP Statute.

However, if a device associated with a computer-implemented creation that includes an aspect addressed by Article 10 of the Brazilian IP Statute is also characterized by its physical components which, through their interconnection or specific technical characteristics perform such functions or methods, this might be open to patent. In this case, it is necessary to ascertain whether there is a contribution in the device characteristics. For example, a pre-paid tariff-charged utility consumption manager that is connected to a remote-controlled device in order to allow the monitoring and control of utilities thereby (water, gas, electricity), although presenting a monetary aspect, namely tariff charges, this is a control system deemed to constitute an invention.

Furthermore, a claim for a device that implements a method falling under Article 10 of the Brazilian IP Statute contains in its descriptive part only the structural characteristics of the device or defines the interconnections between devices might also be open to patent.

The use of terms such as "means to" in the product claim category must not be used when resulting in a lack of definition and clarity. In this case, the claim must specify technically the means claimed, instead of using the expression “means to”, and must include numerical references to the drawings.

If any absence of grounds is noted, the use of the expression “means to” to improperly expand the scope of the protection is forbidden. For example, the use of the expression “data storage media” may not be allowed when the specification defines that, in order for the proposed invention to attain the desired outcome, it is necessary to use a “DRAM memory”, and there are no reasonable grounds for assuming that the invention might function adequately with any type of memory.

When a system claim cannot be defined in structural terms, it may be described in terms of its functionality.

Example: “system for the automatic control of a mechanical gear change transmission, comprised of a fuel choke and a mechanical gear change transmission characterized by the fact that: i) device to detect the effective gear ratio use during each start-up operation; and ii) memory to store the effective gear ratio used during each start-up operation.”
6.4.3 Support Claims

A memory or recording media claim, characterized by contain a computer program is not deemed to constitute an invention as its contents fall under Article 10 of the Brazilian IP Statute. For example, claims of the following type are not accepted: “Recording support read by a computer with a recorded data structure characterized by the above-mentioned computer program, comprised of structures A and B” or “recording support read by a computer characterized by a computer program”. However, memory read by a computer with recorded instructions for running on a computer and encompassing the X, Y, Z steps is deemed to be patentable, if such steps do not fall under Article 10 of the Brazilian IP Statute.

A claim addressing physical support (CDROM, ROM, etc.) containing a mathematical, financial, commercial, accounting, educational, therapeutic or diagnostic method (or a computer program implementing it) does not constitute an invention under item I of Article 10 of the Brazilian IP Statute, as the method is already addressed by this item. However, claims are accepted when referring to a physical support characterized by the fact that it contains the recording of the method addressed in a previous claim, provided that this method is deemed to constitute an invention. In this case, the physical support is not considered to contain a mere presentation of information or computer program.

Should an invention address the physical support itself used to record data, it must be claimed through its physical characteristics and not by the content of the information recorded thereon. Furthermore, supports already known at the state-of-the-art, such as CD, DVD, Blu-ray, pen drive, etc., with an alteration to the data structure, may be deemed to constitute inventions. The use of the expression “means of recording” in the claim is not accepted, as it makes the claim too broad-ranging and ambiguous, as it refers to both the recording method and the physical medium (recording support).

6.5 Summary

The Summary is an effective tool when searching documents, and must allow fast and correct location thereof. The Summary must be concise, presenting the main technical characteristics of the invention and must indicate the technical sector to which it belongs, allowing a clear understanding of the problem and the proposed solution. When illustrated by drawings, the Summary must contain reference marks in brackets, corresponding to the technical characteristics.

7. Definitions

Device claim – a product claim category that is a machine or a device described in terms of its functional capacities or structural characteristics, used to manufacture a product or perform a non-manufacturing activity or process.

Computer – machine or equipment able to process data automatically by a program and generating results. It usually consists of input, output, storage media and arithmetic, logic and control units.

Firmware – computer program recorded in non-volatile memory, for example EPROM, E2PROM (EEPROM) or FLASH memory that handles lower level routines in a microprocessor system, such as BIOS routines, for example.

Flowchart – a graphic representation of a specific workflow or process.
Hardware – physical components, peripheral devices and items of equipment that constitute a computer system, for example: boards, CPU, drives, modem, etc.

Internet – set of networks interconnected by gateways and protocols that allow it to function as a single virtual network.

Methods of doing business – related to commercial, business, accounting, financial, advertising publishing, lottery or fiscal nature methods listed in item III of Article 10 of the Brazilian IP Statute.

Recording media – Physical support, such as floppy disk, CD-ROM and DVD that can be read by computers, where the computer program or data are recorded.

Protocol – set of rules and formats used by two or more computers to exchange information between them.

System – set of units interacting among themselves in order to obtain result(s) that cannot be obtained by any of them working alone.

Virtual – what is done or simulated through electronic media.
This text is an integral part of the Patent Application Examination Guidelines setting out the current understanding of the BRPTO on Biotechnology Inventions. Other inherent exam topics are listed and discussed in the general guidelines.
1. Biotechnology Protection Requirements

The requirements of novelty and inventive step are discussed in the Examination Guidelines for Patent Application. This Annex will highlight only some specific characteristics of biotechnology patent applications.

1.1 Industrial Application

The concept of industrial application in the biotechnology field must comply with the matters set forth in the Examination Guidelines for Patent Application (Block II), and special attention must be paid to the definition of utility for the claimed invention.

When the invention involves biological sequences, the industrial application requirement is met only when some utility is disclosed by the above-mentioned sequence.

Thus, if a patent application identifies a new sequence through homology, with the homologous sequence described in the state of the art having a known function, the new sequence identified in the patent application is liable of industrial application, provided that this utility is identified in the specification.

Example 1: SEQ ID NO: 1 protein was identified in different patients with prostate cancer, and there is no known biological function for this protein in the state of the art. It is ascertained that this protein described in the application is an important marker for the diagnostic of prostate cancer.

Inventions related to this protein (for example, use, composition, diagnostic kit) are suitable for industrial purposes, as the application clearly discloses a practical use for the sequence (marker for in vitro diagnosis of prostate cancer), even if its biological function is unknown.

Example 2: The application discloses a SEQ ID NO: 1 protein that was isolated from yeast, although it does not disclose any function/application for the protein and does not present any homology with a protein whose function is known.

The specification presents a merely speculative list of applications without technical grounds able to provide solid support for any practical application of the protein. This protein and/or its use and/or the compositions that comprise it, are not suitable for industrial application, as these materials do not present any defined practical utility.

2. Protection Conditions

2.1 Unit of Invention

A patent application must refer to a single invention or to a group of inventions so interrelated as to comprise a general single inventive concept (article 22 the Brazilian IP Statute - Statute #9,279/96; see Examination Guidelines for Patent Application, Block I).

Example 3: Multiple nucleic acid molecules that share a common structure and code proteins with common properties.

Claim 1: Modified nucleic acid characterized by being selected from the SEQ ID NO: 1, 2, or 3.
The specification mentions that the three nucleic acids code dehydrogenases that include a conserved motif sequence defining the catalytic site. The three nucleic acids are isolated from three different sources (mouse, rat and human) and modified. The specification clearly shows that these three nucleic acids are homologous, based on their global sequence identity (85% – 95% identity) for both the nucleotide and amino acid sequences.

The same technical or equivalent characteristics that are shared among the nucleic acid molecules are in their common properties (coding dehydrogenases) and their shared structural elements that are essential for their common property (the conserved motif). Consequently, there is a special technical characteristic and SEQ ID NOs: 1, 2, and 3 are endowed with unity of invention.

2.2 SUFFICIENCY OF DISCLOSURE (ARTICLE 24)

Article 24 of the Brazilian IP Statute establishes that the specification must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out (see Examination Guidelines for Patent Application, Block I). It is understood that subject matter means the matter for which protection is sought, meaning the matter contained in the claim chart. Consequently, the analysis of the sufficiency of disclosure of the claimed subject matter must be assessed on the basis of what was disclosed in the specification, sequence listing and drawings (if any).

When the application refers to a product or process involving a biological material that might not be described in a manner whereby a person skilled in the art can understand and reproduce the matter, the specification must be supplemented by the filing of the above-mentioned material (see item 2.2.1).

Two examples of insufficiency of disclosure in the Biotechnology Area warrant special mention. The first is when the embodiment of the invention depends upon chance. In this situation, even if a skilled technician follows the instructions given in the application, there is no guarantee of obtaining the alleged results. These cases must be questioned, pursuant to the provisions set forth in article 24 of the Brazilian IP Statute (see item 2.2.1.1 and example 4). The second is when the embodiment of the invention is inherently impossible. For example, in a method that includes the amplification of a specific DNA sequence through the use of a specific pair of primers, in which these primers are not complementary to any part of the DNA sequence is not a method that can be performed.

Example 4: The application describes a mutant microorganism obtained through random mutagenesis with UV radiation. As obtaining the microorganism is dependent on random chance, the sufficiency of disclosure of the microorganism will be complied only by filing the microorganism (see item 2.2.1.1). The document proving the filing of the microorganism in question may be presented through clarifications during the technical examination, provided that the filing of the microorganism occurred up to the filing date of the application (or the priority date of the application, if any). The microorganism obtained through UV-induced mutation and filed in this manner will not fall under article 10 (IX) provided that there is no evidence that a microorganism with the characteristic is found in nature.

Example 5: The application describes a new and inventive method of obtaining mutant microorganisms through random mutagenesis. As the stages of the above-mentioned method are described in detail in the specification, it is possible for a person skilled in the art to reproduce the invention. Consequently, this method presents sufficiency of disclosure, complying with the provisions set forth in article 24 of the Brazilian IP Statute. Should this method be related to obtaining only a single mutant with specific characteristics, the information of the filing thereof must be set forth in the claim, as there is no guarantee of obtaining such outcomes.
Example 6: The application describes a method that uses a mutant microorganism. The specification does not provide details on the process of obtaining the microorganism, but characterizes it through its respective filing number. In this case, it is considered that the person skilled in the art could reproduce the method in question using the filed microorganism. Thus, the invention complies with the sufficiency of disclosure condition.

Example 7: The specification discloses a protein through its NCBI-sequence database access number or through reference to a scientific paper, with this protein being essential for the embodiment of the invention. In order to comply with the sufficiency of disclosure requirement set forth in article 24 of the Brazilian IP Statute, the applicant is required to include the sequence in question in the application, as disclosed in the database at the time of filing/priority date, presented as a sequence listing, without this resulting in the inclusion of additional matter, as this protein may be identified quite clearly through its access number or the above-mentioned scientific paper (see additionally items 2.2.1.1 and 2.2.2).

Example 8: The application describes a new dopaminergic receptor duly characterized through its amino acid sequence. The application mentions that the antagonists and agonists of the receptor are also useful. However, the application does not provide a technical description of any of the receptor antagonist and agonist compounds. The person skilled in the art would not be able to execute the invention related to the antagonists and agonists due to the lack of technical instructions on how to do so, as the mere description of a receptor does not provide sufficient information on the molecules that could stimulate or inhibit its function. Thus, it is understood that the subject matters related to the enzyme antagonists or agonists do not comply with the sufficiency of disclosure condition (see also item 3.1).

2.2.1 Deposit of Biological Material

Should biological material be essential for the practical implementation of the object of the application, which can not be described in compliance with article 24 and when not accessible to the public, the specification shall be supplemented by filing the material at an institution authorized by the BRPTO or indicated under an international agreement (Budapest Treaty; see Examination Guidelines for Patent Application, Block I).

In this context, “biological material” may refer to any material containing genetic information and capable of self-replication (direct or indirect). Representative examples include bacteria, archaea, protozoa, virus, fungus, algae, seeds, animal and plant cell lines, hybridomas, artificial chromosomes and other vectors; in some of these cases and depending on the requirements of the selected filing centre, the host cell containing these biological materials may be filed.

2.2.1.1 Cases in which a Biological Material must be Filed

It is important to stress that, as mentioned above, the Brazilian IP Statute refers to the filing of biological material that might not be described as set forth in article 24, meaning that it might not be described in a clear and sufficient manner in the specification. It is thus concluded that the filing of the material does not necessarily apply to all and any biological material involved in a specific invention. For example, polynucleotides and polypeptides, must be described through their nucleotide and amino acid sequences (note: nevertheless, there is nothing that prevents such materials to be additionally filed).

With regard to microorganisms with nucleotide sequences different from those found in nature, the application must present the modified nucleotide sequence through the sequence listing (see item 2.2.2), or its denomination
as known at the art, or the microorganism filing data. When essential for ascertaining inventive characteristics, specific promoters, the place of insertion in the genome of the heterologous material, the methodology for obtaining the sample, among other essential characteristics, must also be present in the description, in order to allow a person skilled in the art to implement the invention.

In cases where the microorganisms are selected through random mutagenesis and the genetic alterations that result in a outstanding effect are not defined in the application, in order to comply with article 24 of the Brazilian IP Statute, the microorganism must have been filed with an international filing authority, and the filed data (such as filing declaration or name of the institution, with the number and date of the filing) form part of the application (see item 2.2.1). Thus, the biological material will be available at the filing authority and shall consequently be considered as being clearly and sufficiently described, as well as replicable. Should the microorganism not have been filed, the matter will not be in accordance with article 24 of the Brazilian IP Statute.

When the inventive characteristic obtained through genetic alteration is achieved only with a specific strain used in the application under examination, it is considered that the microorganism per se is essential for the implementation of the invention and it is consequently necessary to file the biological material in order to ensure that the matter complies with article 24 of the Brazilian IP Statute. On the other hand, it is not necessary to file the biological material when the inventive characteristic might be achieved with several available strains or species of microorganisms using the methodology described in the application. Thus, for situations in which widely known organisms are merely transformed in order to express a new and surprising characteristic, it is sufficient to indicate the organism of interest, relating specifically to the nucleic acid to be used in this transformation, and ensuring that this nucleic acid is described in a clear and accurate manner.

In cases when the invention does not lie in a microorganism or a biological material per se, but its use, modification or culture thereof, and a person skilled in the art is unable to perform the invention without having the sample mentioned in the application, the filing of the microorganism or the biological material shall also be necessary.

### 2.2.1.2 Deadlines for Filing a Biological Material

With regard to the original filing of biological material for patent purposes, Normative Instruction IN PR #17/2013 establishes that the biological material must be filed until the filing date of the patent application, and that this data must be included in the specification. Should there be a Paris Union priority, the biological material must be filed prior to or by the priority date claimed, if pertinent, in other words, if the priority rights are applicable to the biological material.

When the evidentiary data on the filing of the biological material are not presented in the patent application, and the patent examiner deems such data necessary, a technical requirement must be issued for the applicant to reply. Should such requirement not be complied with, the application must be rejected, grounded on article 24 of the Brazilian IP Statute.

### 2.2.2 Sufficiency of Disclosure of the Sequence Listings

The patent application whose object contains one or more nucleotide and / or amino acid sequences that are crucial for the description of the invention must contain a sequence listing section in order to comply with the sufficiency of disclosure addressed in article 24 of the Brazilian IP Statute (see Examination Guidelines for Patent Application, Block I). It is stressed that, should the application use and refer to sequences known in the art and
should they be necessary for the embodiment of the invention, the patent examiner may issue a requirement ordering the sequences to be presented. It must also be noted that the sequences must correspond to those known as the state of the art at the time of the filing/priority date (i.e., as disclosed in the data bases), taking into account possible refinements or alterations in the sequences over time.

Rule #228/09 issued by the BRPTO and included in Rule PR #81/2013 also issued by the BRPTO, governs the procedures for the presentation of the sequence listing on electronic media, replacing item 16.3 of Rule #127/97 (see Rule PR #81/2013 and the Annexes appended thereto and published in the Federal Official Gazette (DOU) – §1, #68, April 10, 2013).

2.3 Support, Clarity and Accuracy (article 25)

2.3.1 Support in the Specification

The subject matter for which protection is sought must be duly supported in the specification. To do so, the description presented through the specification must provide technical information able to provide solid support for all the claimed matter.

Example:

Claim 1: Immunogenic protein characterized by consisting of SEQ ID:1, and its fragments.

The specification presents a mutated immunogenic protein (not natural) of 600 amino acids residues and also discloses an immunogenic fragment of this mutated protein (not natural), determined as consisting of residues 320 to 400 of the above-mentioned protein. In term, the claim chart requests protection for the immunogenic protein and for the immunogenic fragments of this protein (claim 1). However, the specification discloses only an immunogenic fragment of this protein, namely: the one that begins at position 320 and ends at position 400 of the protein. In this case, as the patentability requirements set forth in article 8 of the Brazilian IP Statute have been complied with, a requirement must be issued on the basis of articles 24 and 25 of the Brazilian IP Statute, whereby the claimed matter shall be limited to only that sufficiently described and effectively supported by the specification, which is an immunogenic protein and its fragment which comprises the residues 320 to 400 of this protein.

In this example, even if the applicant presents new information on other immunogenic fragments of the above-mentioned protein that have not been described in the matter initially disclosed, this information may not be taken into consideration, as the specification did not mention other immunogenic fragments of this protein different than that comprised between the amino acids 320 and 400 of the protein. Consequently, the fact remains that the claim for broad-ranging protection of “immunogenic protein fragments” may not be accepted due to the absence of sufficiency of disclosure and adequate support for the matter in the specification.

Example:

Claim 1: Process of plant transformation characterized by the introduction of the gene X into angiosperms and gymnosperms.

The specification presents general information on the process and a detailed example of the transformation of the
gene into an angiosperm. There is evidence for a person skilled in the art that this process would not be applicable in the same manner to both groups of plants, and consequently the claim including gymnosperms would not be supported by sufficient information in the specification. This lack of support could be overcome through evidence that the transformation of gymnosperms could be carried out under the same conditions already mentioned for angiosperms.

However, should the data supplied in order to present sufficient support for the gymnosperm claim, introduce new parameters or any non-trivial adaptations for a person skilled in the art, such information may not be accepted. This is because the data must be included in the specification, which would constitute an addition of matter, thus not complying with article 32 of the Brazilian IP Statute.

3. Claims

There are two basic types of claims: product claims, related to a physical entity; and process claims, related to an activity (see Examination Guidelines for Patent Application, Block I).

In the biotechnology area, some non-exhaustive examples of subject matter considered to fall in the “products” category are: nucleic acids, peptides, polypeptides, proteins, microorganisms, virus, cells, vectors, plants, seeds, hybridomas, antibodies, probes, vaccine compositions, kits, expression cassettes, extracts, food products and others. For “process claims”, some non-exhaustive examples are: process to produce a compound/composition; process for selecting a nucleic acid/polypeptide/peptide sequence; process to produce a transgenic microorganism/plant/animal; purification method; extraction/isolation processes, among others.

3.1 Reach-through Claims in Biotechnology

The reach-through claim is a special type of claim that is designed to provide protection for future inventions based on a current invention. In other words, this type of claim is intended to provide protection for inventions that have not been identified by the inventor by the filing date of the patent application, but that might be identified in the future through the use of the actual invention.

A frequent type of reach-through claim in biotechnology is the product claim, with the product in question generally corresponding to a “candidate compound”. These claims are designed to protect compounds that are candidates for modulators of the real invention activity, such as agents modulating a biological function of a protein or a gene.

Reach-through products (drugs, agonists, antagonists, etc) are usually identified only by reference to a material or method used in the identification thereof, without defining their chemical structures. Alternatively, these products are defined in terms of a function associated with the actual invention, as this is the only information available to the inventor. Consequently, both the compounds that are already known at the state of the art as well as those that are still to be identified are encompassed by the scope of the claim, which thus becomes quite broad-ranging.

Another type of reach-through claim in biotechnology is the modular compound identification process claim. For this type of claim, the compound identified by the process is not defined through its structure but rather by its capacity to modulate the expression of a protein or gene involved in a disease, for example, or the screening method that is used to identify this compound. The common characteristic for these types of claims is that the material to be protected is not known.
3.1.1 Technical Examination of Reach-through Claims

The subject matter addressed by reach-through claims typically do not present sufficiency of disclosure, clarity, accuracy and / or support, thus not complying with articles 24 and 25 of the Brazilian IP Statute.

Example 11:

Claim 1: Process for identifying an agonist/antagonist of polypeptide X characterized by comprising: (a) contacting the polypeptide in question with a compound to be traced; and (b) determining whether the compound affects the activity of the polypeptide in question. Claim 2: An agonist/antagonist characterized by being for polypeptide X as identified through the process defined in claim 1.

This application refers to a new and inventive screening process for modulators of activity of a polypeptide already known in the state of the art (polypeptide X), whose activity was demonstrated as being involved with disease Y, although without characterizing the compounds identified by this process.

Claim 1 defines the main invention of the application, which is a method of screening compounds of therapeutic interest and that modulate the activity of polypeptide X, which constitutes the actual invention, while Claim 2 is a reach-through type that, in this situation, may include in its scope compounds that are already known and not modified in any manner whatsoever by the process used in their identification, as well as compounds that are not yet known.

Although the application describes the screening process specified in claim 1 in a sufficient manner, and may thus be accepted for this aspect, claim 2 is not accepted due to the lack of sufficiency of disclosure (article 24), clarity, accuracy and support (article 25). Claim 2 uses functional (rather than structural) characteristics to define the matter for which protection is requested. However, the definition of a product through functional characteristics frequently results in a lack of clarity for the matter addressed thereby. A person skilled in the art would not be able to implement the definition of the claimed subject matter, because the compounds claimed per se (claim 2) offer potentially unlimited structural possibilities, thus including compounds that are still to be identified and / or that are already available at the state of the art and / or that are encompassed by the prohibitions set forth in article 10, IX.

Claim 2 requests protection for candidate compounds identified through the screening method of the invention as defined in claim 1. These compounds were technically defined only through their activity (meaning a functional definition – wording that is common to this type of claim) which in this situation corresponds to a modulation (agonist/antagonist) of the activity of polypeptide X. The structural characteristics of the candidate compounds were not defined; this situation would force said person skilled in the art to test countless compounds that are already known as well as all compounds that could be identified in the future using the screening method of the invention, in order to determine which of the compounds would have the desired activity and would thus be encompassed by the scope of the claims under examination.

4. Subject Matter Excluded from Protection under The IP Statute

4.1 Definitions

Pursuant to the understanding adopted by this Institute, from the technical standpoint, the terms and expressions used in this item are construed in the following manner:
• “whole” (natural living beings) refers to plants, animals, microorganisms and any living being;
• “part of natural living beings” refers to any portion of living beings, such as organs, tissues and cells;
• “biological materials found in nature” encompasses the whole or part of natural living beings, in addition to extracts, lipids, carbohydrates, proteins, DNA, RNA, found in nature or isolated therefrom, as parts or fragments thereof, as well as any substance produced through biological systems, such as hormones and other secreted molecules, viruses or prions. It is worthwhile stressing that synthetic molecules that are identical to or indistinguishable from their natural counterparts are also encompassed by this definition;
• “isolated from nature” is all and any subject matter extracted and run through an isolation or purification process, i.e. that removes it from the natural context;
• “genome” is the set of genetic information of a cell, organism or virus;
• “germplasma” is the set of hereditary material of a representative sample of individuals belonging to the same species;
• “natural biological process” is any biological process occurring spontaneously in nature and where human intervention does not affect the final outcome;
• “therapy” is a method of treatment designed to cure or prevent a disease or faulty functioning of the body;
• “surgery” is defined by the nature of the treatment instead of its purpose, meaning regardless of whether the manual or instrumental intervention in the patient’s body is undertaken for aesthetic or therapeutic purposes; and
• “diagnosis” refers to the identification of a specific disease.

4.2 Subject matter not considered as Inventions (article 10)

4.2.1 Natural Biological Products and Processes (Article 10 (IX))

With regard to claims in the “product” category, article 10 (IX) of the Brazilian IP Statute stipulates that it is not considered invention the whole or part of natural living beings and biological material when found in nature, or isolated therefrom, including the genome or germplasma of any natural living being.

For claims in the “process” category, such as processes, methods, uses, applications, among others, article 10 (IX) of the Brazilian IP Statute refers solely to natural biological processes, ruling that they are not considered to constitute inventions.

As article 10 (IX) of the Brazilian IP Statute stipulates that the whole or part of natural living beings and biological materials found in nature that are not deemed to constitute inventions, documents published subsequent to the priority /filing date of the application under analysis may be used, in order to prove that the claimed subject matter falls under the provisions set forth in article 10 (IX) of the Brazilian IP Statute, provided that the information submitted clearly proves, without a shadow of doubt, the existence in nature of the claimed subject matter.

4.2.1.1 Natural Biological Products

The whole or part of natural living beings and biological materials found in nature – even if isolated therefrom or produced in a synthetic manner that have natural counterparts occurring in nature with no way of distinguishing them from their natural counterparts –, are considered as natural biological products and shall not be deemed to constitute inventions, as they are fall under the provisions set forth in article 10 (IX) of the Brazilian IP Statute.
Thus, the inclusion of a disclaimer with the expression “not natural” does not rebut, in itself, the objection raised grounded on article 10 (IX) of the Brazilian IP Statute.

4.2.1.1 Compositions containing Natural Biological Products

A composition claim whose sole characteristic is the presence of a specific product also confers protection on this product per se. Thus, a composition claim that is characterized only by containing a non-patentable product (for example, a natural extract), might not be granted, as this would protect the non-patentable product itself. That is, with more grounds here than for patentable components, such claims require parameters or characteristics that clearly determine, without a shadow of doubt, that this is an actual composition.

In these cases, special care must be taken with the wording of the claim in terms of the other component(s) of the composition in question, in order to avoid that it merely represents a mere dilution, on the bottom line (an aqueous solution, for example) of the non-patentable product. Bearing in mind that the purpose of a composition is to place the active component(s) in an appropriate manner to the purpose for which it/they is/are intended, a “mere dilution” would consist of the solvent not contributing to this final purpose, being merely the means used for the extraction. Consequently, it is possible that a water-based or ether-based extract from a specific plant, for example, although containing a component (extraction solvent) in addition to the extract itself, does not represent a composition ready for use in terms of its final purpose, and this same diluted extract in some other solvent (for example, used to make the active ingredient absorbable) represents a de facto composition, rather than a “mere dilution”.

4.2.1.2 Extracts

Extracts are biological materials isolated from nature and are, consequently, not deemed to constitute inventions, based on article 10 (IX).

Thus, for extracts-containing compositions, the same remarks are valid as presented above for natural products.

4.2.1.3 Enriched Extracts

Extracts that differ from their natural counterparts through being enriched by some of their components are liable to protection only when presenting in their composition characteristics that cannot be attained normally by the species and that arise from direct human intervention.

Attention must also be paid to the issue of extracts of transgenic bacteria cells. Although the microorganism per se might be patentable, this might not always apply to its extract, as cases might occur where it is not possible to distinguish the transgenic cell extract from the wild extract (for example, when the transgenic microorganism merely super expresses an endogenous protein.).

Example:

Claim 1: Plant extract characterized by being enriched with isoflavones

The extract is enriched with isoflavones through the isolation method. In this case, it is considered that the modification
of such extract is the result of the simple fractioning of a natural extract isolated from nature, and this claim, consequently, falls under article 10 (IX).

Example: Extract enriched through genetic manipulation

Claim: Enriched plant extract characterized by comprising human insulin.

The application describes a process of alteration in the composition of the plant extract through expression of the human insulin gene, resulting in an enriched extract. In this case, it is considered that the modification of such extract is the result of genetic manipulation of the organism from which it is extracted. Thus, as this material is obtained from plants presenting characteristics that cannot be normally attained by the species, arising from direct human intervention, this extract is open to protection.

4.2.1.2 Natural Biological Processes

“Natural biological process” means any biological process occurring spontaneously in nature and where human intervention does not affect the final outcome.

If the technical intervention plays an important role in determining the outcome or should its influence be decisive, the process is considered as an invention. That is, the processes that contain at least one technical stage with a decisive impact on the final outcome and that might not be achieved without human intervention, are considered to constitute inventions.

Regarding this concept, the classic process of obtaining plants or animals is not an invention. Similarly, processes that encompass only stages mimicking events that occur in nature are also not considered to constitute inventions. In contrast, methods based on genetic engineering (for example, the production of a transgenic plant), wherein the technical intervention is significant, are liable of patent protection.

Microbiological processes encompass processes that use, are applied to, or result in microorganisms. Although these processes are biological processes, the BRPTO considers that they are allowable as they constitute an exception to the legal exclusions permitted in the TRIPS Agreement (Article 27 (3b)).

Similarly, the BRPTO considers that biological or enzyme-based processes for obtaining chemical compounds are liable of patent protection when presenting a technical stage that is decisive for the final outcome.

Similar to other processes, biological processes claims correctly drafted define the starting material, the product obtained and the means for transforming the former into the latter; the various stages needed to attain the proposed objective or; in the case of use, the material to be used and the purpose of this use.

Examples of acceptable claims (note: the level of detailing required will depend on the specific invention under examination):

- Process for obtaining compound X characterized by cultivating microorganism W (bacteria, fungus, yeast, etc.) on Y.
- Process for obtaining compound X characterized by using an Enzyme E.
- Process for obtaining compound X characterized by cultivating plant P cells transformed with gene T.
4.2.1.3 Use of Natural Products

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 hampering its patentability under the provisions set forth in article 10 (IX) of the Brazilian IP Statute. Thus, the use of a natural product might be liable of patent protection, provided that it complies with the patentability requirements.

Example 14:

Claim: Use of a natural resin obtained from Aloe vera plant leaves characterized by being in the preparation of cosmetic compositions for the treatment of keratin fibers.

Claims related to the use of natural resin for the preparation of cosmetic compositions may be accepted, when compliance with patentability requirement is ascertained, as there is no article in the Brazilian IP Statute preventing the use of natural products in activities that do not constitute natural biological processes.

Example 15:

Claim: Use of RNAse characterized by being in the cleavage of the RNA.

Use of natural material for performing the specific natural function is not considered to constitute an invention under article 10 (IX), as it consists of a natural biological process.

4.3 Non-patentable Inventions (article 18 of the Brazilian IP Statute)

4.3.1 Non-patentable Inventions under article 18 (I) of the Brazilian IP Statute

Pursuant to article 18 (I), “that which is contrary to morals, good customs and public security, order and health” are not patentable.

As biotechnology is a technological field generating inventions that involve matters that could raise moral issues and matters of public order, the current doctrine allows the BRPTO to refuse to patent such inventions, grounded on article 18 (I) of the Brazilian IP Statute.

The following examples are non-exhaustive:

- processes cloning human beings;
- processes modifying the human genome that result in modifications to the genetic identity of human germinative cells; and
- processes involving animals that cause suffering thereto, with no substantial medical benefit for human beings or animals resulting from such processes.

In claims with the wording “Processes for cloning mammal cells”, it is understood that the word “mammal” includes human beings. Thus, such a claim might adversely affect public morality, order and health and would consequently
contravene article 18 (I) of the Brazilian IP Statute. In this case, the exclusion of human mammals from the scope of the protection would be an acceptable disclaimer, even if human beings were not excluded in the original specification.

4.3.2 Non-patentable Inventions under Article 18 (III) of the Brazilian IP Statute

Pursuant to article 18 (III) of the Brazilian IP Statute, “living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements - novelty, inventive step and industrial application - provided for in article 8 and which are not mere discoveries” are not patentable.

With regard to transgenic microorganisms, the sole ¶ of article 18 (III) of the Brazilian IP Statute states that: “For the purposes of this statute, transgenic micro-organisms are organisms, except the whole or part of plants or animals, which exhibit, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by the species under natural conditions”.

Pursuant to this definition, the expression transgenic microorganism encompasses microorganisms (see item 5) that are obtained through any technique whose outcome is an alteration in the genetic composition that is not attainable by the species under natural conditions, through direct human intervention. This definition is not limited to microorganisms in which genes have been inserted that are exogenous and / or from other organisms.

In order to examine claims for transgenic microorganisms, it is initially necessary to ascertain whether, in the description of the application, the term “microorganism” encompasses animal and plant cells which are not liable of patent protection, as the whole or part of plants and animals is not patentable, even if transgenic. In these cases, the claimed subject matter must be limited in a manner that encompasses only transgenic microorganisms liable of patent protection. Furthermore, the human intervention must be clear in order to assess whether this does, actually, refers to a microorganism that expresses a characteristic normally not attainable by the species under natural conditions.

Denominations such as “transgenic”, “mutant” or “variant” are not sufficient to ascertain the patentability of the microorganism, as there is a possibility of the microorganism, although referred to as “transgenic”, “mutant” or “variant”, to occur naturally or to be indistinguishable from its natural counterpart and, thus, not constitute an invention under article 10 (IX) of the Brazilian IP Statute.

5. Microorganisms

The generic term “microorganism” is used for bacteria, archaea, fungus, single-cell algae not classified in the Plant Kingdom and protozoaria. Thus, among the whole or part of living beings, whether natural or transgenic, the Brazilian IP Statute only allows the patenting of transgenic microorganisms.

Examples of appropriate formulations for microorganism claims (non-exhaustive list)

- Transgenic microorganism characterized by containing the SEQ ID NO: X.
- Transgenic microorganism characterized by containing the SEQ ID NO: X inserted in the Y position of the genome.
- Transgenic microorganism characterized by containing the xxxxxxxx sequence in the Y position of the genome (see item 2.2.2).
• Transgenic microorganism characterized by containing the X gene (provided that the gene is well known).
• Transgenic microorganism characterized by containing the X gene with the Z promoter inserted at position Y of the genome (provided that the gene and the promoter are well known).
• Transgenic microorganism characterized by containing the expression vector X (provided that this vector is well known).
• Transgenic microorganism characterized by being the ATCC-XXXX (filing number).

Attention must be paid when SEQ ID NO: X, gene X or plasmid X were isolated from a natural microorganism and not modified. In this case, a claim with a generic title of “microorganism” or “bacteria”, among others, will also protect the original microorganism that naturally has the above-mentioned gene, and will be subject to objection under the provisions set forth in article 10 (IX) of the Brazilian IP Statute.

6. Biological Sequences

In general, for patent applications that describe an invention whose development depends on amino acid and/or nucleotide sequences, the following aspects must be noted: (i) the need to include the sequence in the application for the purposes of sufficiency of disclosure (article 24); (ii) natural occurrence (article 10 (IX)); (iii) clarity, accuracy and support (article 25) in the manner in which such molecules/sequences are claimed; (iv) novelty (article 11); (v) inventive step (article 13); and (vi) industrial application (article 15).

The sufficiency of disclosure for biological sequences is addressed specifically in item 2.2.2.

The novelty requirement, when related to biological sequences, follows the same general principle (see Examination Guidelines for Patent Application, Block II), meaning that for an amino acid or nucleotide sequence not to meet the novelty requirement in view of the state of the art, all the amino acids or nucleotides must be exactly the same and be in the same order and, additionally in some cases, have the same structural formula as the sequence known in the art.

Other points that inadequacies are usually found are discussed in the following topics.

6.1 How to Characterize

Having complied with the rules established in item 2.2.2 as a way of ensuring the clarity and accuracy of the claimed subject matter, the claim chart must refer to the biological sequences in question through the corresponding SEQ ID NO: (see item 2.2.2).

In some cases, other forms of characterization for biological sequences may be accepted:

a. when the sequences are shorter than four amino acids or ten nucleotides, pursuant to Rule PR #81/2013, they must be characterized by the specific sequence;
b. structural formulas accompanied by their corresponding SEQ ID NO:;
c. Markush formulas accompanied by their corresponding SEQ ID NO:;
d. number of filings (see item 2.2.1); or

e. their name or designation, when the biological sequence is already known at the state of the art and is not the main purpose of the invention.
It is stressed that a DNA must be defined through its nucleotide sequence, while a protein must be defined through its amino acid sequence, in order to clearly define the matter presented for protection.

Moreover, attention must be paid to claims of the following types, as none of them presents clarity (article 25).

a. DNA sequence characterized by coding a protease.
In this type of claim, the product is characterized only by its function, that is not sufficient to clearly define which product it refers to. On the other hand, if this DNA is characterized by its nucleotide sequence, the definition of the function may be accepted, as an additional characteristic of the product.

b. DNA sequence characterized by coding a polypeptide presenting the amino acid sequence of the protein represented by SEQ ID NO: 1.
This wording defines a DNA through the amino acid sequence, which is not permitted. However, the claim may be altered in a manner that defines the DNA through the nucleotide sequence, with their degeneration being accepted, which generates the same protein. In this situation, at least one nucleotide sequence must be present in the application as filed, unless it is a sequence that is already available in the state of the art and is mentioned in the specification.

c. Protein characterized by presenting the Y activity.
The product is characterized only by its function, which does not allow a clear definition of its scope. On the other hand, if the above-mentioned protein is characterized by its amino acid sequence, the definition of the function may be accepted, as an additional characteristic of the product.

d. Protein with the Y activity characterized by presenting the following amino acid composition: (percentage of each amino acid).
In this type of claim, the product is characterized by its function and percentage of amino acid, which also does not allow a clear definition of the claimed product. The amino acid sequence is necessary.

e. Plasmid characterized by being the pWn.
In this type of claim, the product is characterized by a designation given by the inventor, which does not allow a definition of the product.

6.1.1 Markush Sequences

Biological sequences may be presented in the form of a Markush formula containing a base sequence that is substituted by one or more variable sub-structures, which are accompanied by a list of definitions of these variable portions, such as:

Formula 1 peptide

Xaa1, Xaa2 His Xaa4 Pro Gly Ser Phe Ser Asp Glu Gly Asp Trp Leu;

wherein

Xaa1 is His or Thr;
Xaa2 is Ala, Gly or D-Cpa (4-chloro-Phe); and
Xaa4 is Gln, Asn or Pro.

For further details on Markush formulas, see the Examination Guidelines for Patent Application, Block II.
6.1.2 When the Sequence Listing must be Filed with the Application

Rule PR #81/2013 issued by the BRPTO establishes in its article 2 that when the patent application contains one (or more) nucleotide and/or amino acid sequence(s) that is/are fundamental for the description of the invention, this/these sequence(s) must be presented in a sequence listing.

When the invention includes the sequence per se, that is, when the claim chart includes claims for “protein,” “polypeptide,” “nucleic acid,” or any other term designating a biological sequence, this is considered a fundamental part of the invention, and must be included in the sequence listing (except for sequences of less than four amino acids or ten nucleotides, pursuant to the definition set forth in Rule PR #81/2013).

On the other hand, when the molecule in question is only an illustrative example, this specific sequence may not be considered as a fundamental part of the invention, and consequently, this sequence does not, necessarily, need to be presented as part of the application.

Furthermore, attention must be given to the possibility that other sequences used in the application – but not necessarily the coding genes/sequences – are fundamental for carrying the invention out. Thus, even in these cases, attention must be paid to whether the sequence in question is widely known at the art, and whether its use is fundamental for carrying the invention out.

6.1.3 Need to Limit the Claim Chart to the Sequences Filed with the Application

When the sequence in question merely represents a molecule that is part of a described process, but any other molecule with the same biological function would present the same outcome (or in situations where there is no reason to believe that such molecules will not be effective), this method does not necessarily need to refer to a single SEQ ID NO; as this would unnecessarily limit the scope of the method in question.

Example16: The application describes a method for inducing sporulation in bacteria characterized in that such bacteria are transformed by a vector containing the sporulation gene under the control of any promoter. Examples presented in the application use the spo5 gene, however, any gene in the spo family would, theoretically, allow the same outcome to be attained. Thus, in principle, there is no reason to present the specific sequence of the spo5 gene in the claim for such method.

Attention must be paid in these cases to the “generic” name given to the sequence of interest, such as “spo gene”, as mentioned above, if the applicant uses such denomination in the claims, it must be widely known and used at the art, unmistakably referring to a specific gene family.

Example17: Method for inducing the expression of a specific gene under stipulated specific conditions.

The specification makes it clear that the desired characteristic is gene expression under a specific condition, which is attained only through the use of a promoter X, as this promoter is only activated when the medium achieves certain characteristics of interest (glucose depletion, for example).

The application describes the use of different genes under the control of this promoter X, demonstrating that all of them are expressed only under the conditions of interest.
In this case, the only fundamental sequence for obtaining the desired characteristic is that of the promoter X. Consequently, similar to the previous example, the presentation of the sequences of the genes used is not mandatory; and even if the applicant has presented such sequences, it is not considered to be necessary that the claimed subject matter should be limited to these genes. However, the promoter sequence, which is the invention, must be described in a clear and precise manner through its corresponding SEQ ID NO.

6.2 Homology versus Identity

When aligning and comparing nucleotide or protein sequences among themselves, the terms homology, identity and similarity may be employed. Initially, it is appropriate to point the correct distinction among these terms here.

Two sequences (of nucleotides or amino acids) are homologous only when they share a single common ancestor. Thus, the concept of being “partially homologous” does not exist: two sequences are either homologous or not, being incorrect to mention percentage of homology. Homologous proteins generally share many similarities in their three-dimensional structures. When two sequences are homologous, they generally share a significant identity, with the opposite also occurring: two molecules may be homologous without sharing any statistically significant identity between their amino acid or nucleotide sequences (for example, as is the case of the globins family).

The establishment of homology between two sequences is not based only on the analysis of the identity between these sequences, but also on biological criteria, such as analyses of the structure and functions of the proteins, for example. Results of sequence comparisons through algorithms such as BLAST, FASTA and SSEARCH do not evaluate homology between sequences: they measure the similarity and identity among sequences. While homology refers to a qualitative inference, identity and similarity are quantitative attributes.

The identity between two sequences refers to the occurrence of exactly the same nucleotides or the same amino acids in the same position in two nucleotide or protein sequences that are aligned and compared. Thus, if two proteins present 90% identity, this means that 90% of all the amino acid residues in the above-mentioned proteins have identical corresponding positions.

On the other hand, the percentage of similarity between two protein sequences refers to the sum of identical and similar matches (for example, the glutamate and aspartate amino acids are considered as similar, as both are acidic). It must be noted that similarity might be measured on the bases of different definitions of how closely related (similar) one amino acid residue is to another.

Applying these terms to the examination of patent applications, the following types of claims are not accepted:

a. claim such as “protein (or DNA sequence) characterized by being the SEQ ID NO: 1 or any other amino acid sequence with at least x% homology with SEQ ID NO: 1” is not clear (contravening the provisions of article 25 of the Brazilian IP Statute), as, technically, the term “% homology” is not applicable, as stressed above; and b. claim such as “DNA (or protein) sequence characterized by presenting at least 80% identity (or similarity) with SEQ ID NO: 1” cannot be accepted as the manner in which it is worded encompasses countless different sequences, not even specifying at what locations on the nucleotides (or amino acid) sequence such substitutions might occur; consequently, claims of this type may not be accepted, as the characterization of the object of the protection is not clear and precise, contravening article 25 of the Brazilian IP Statute.
Additionally, the characterization of the sequence of interest based on the identity percentage is very broad-ranging and generally includes in its scope sequences that are not supported by the specification or that fail to comply with the patentability requirements. Finally, it must also be noted that in these cases the specification generally does not provide sufficient information allowing the replication of all the countless sequences encompassed by this type of definition (contravening article 24 of the Brazilian IP Statute).

### 6.3 Nucleotide Sequences

Nucleotide sequences may be mentioned in patent applications in different ways: genes, vectors, plasmids, DNA sequence, RNA sequence, nucleic acid, oligonucleotides, primers, cDNA, and others. However, for the purposes of simplification, in these Guidelines, all these molecules shall be generally called “nucleotide sequences”. This definition is valid, regardless of the size of the above-mentioned molecule. The following items discuss the particularities of some of these molecules.

These nucleotide sequences must be characterized as set for in item 6.1. However, it must be stressed that molecules defined by a sequence of at least ten nucleotides must be characterized by its specific nucleotide sequence.

#### 6.3.1 Modifications of Nucleotide Sequence(s)

Modifications of nucleotide sequences intended to distinguish them from natural sequences may be performed in different ways. In principle, any characteristic introduced in the sequence that is not described as naturally occurring is accepted as a modification, so as not falling under article 10 (IX) of the Brazilian IP Statute, and compliant with the provisions set forth in item 6.3.1.1. However, merely introducing terms such as “recombinant” in natural molecules claims can not be accepted, as the resulting molecule would be indistinguishable from its natural counterpart, even if produced in a recombinant manner.

##### 6.3.1.1 Modifications of Sequence(s) through Substitutions, Insertions or Deletions of Non-Modified Nucleotides

In general, modifications of natural biological sequences through the insertion of non-modified nucleotides in the sequence (in the middle or at the ends) are considered sufficient to avoid falling under article 10 (IX), provided that the resulting sequence formed does also not occur naturally.

Should the nucleotides be deleted in the middle of the claimed sequence, this modification is, in principle, sufficient to distinguish it from the natural molecule. However, even if the deleted nucleotides are contiguous and at the end of the sequence this still falls under article 10 (IX), as the resulting sequence would still continue to be identical to a part of the natural sequence (see item 6.3.2).

With regard to the substitution of nucleotides by other non-modified nucleotides, it is considered that this modification is sufficient to avoid falling under articles 10 (IX), provided that there is no description of natural sequences (for example, in related species) containing such substitution.

However, it must be borne in mind that assorted substitutions of nucleotides in a given sequence may not result in any modification in the protein encoded by this sequence, due to the degeneration of the genetic code. Consequently, in these cases, a nucleotide sequence modified by substitutions might not fall under article 10 (IX),
while the amino acid sequence encoded by this sequence remains identical to its natural counterpart, consequently falling under article 10 (IX).

When analyzing sequences derived from the state of the art that are not encompassed by article 10 (IX), the inventive step of the modification carried out (insertion, deletion or substitution) must be assessed carefully, taking into account the fact that some groups of amino acids present common properties. Thus, the inventiveness of these alterations in the polynucleotide sequences, in general, depends on the demonstration of an unexpected effect generated by the modification compared to the state of the art.

### 6.3.1.1 SNPs

The SNP acronym refers to a “single nucleotide polymorphism”, and is used to designate natural variations that occur in the genome and which involves a single nucleotide, as the name indicates. This may be associated with certain characteristics, thus serving as molecular markers.

Regardless of the described use, whenever a specific SNP – or any other polymorphism – is described as naturally occurring, it may not be considered as an invention under article 10 (IX) of the Brazilian IP Statute. However, the use of a set of SNPs, for example, in an in vitro diagnostic method (such as DNA fingerprinting) or in the personalized medicine field, might be liable of patent protection.

### 6.3.1.2 Modification of Nucleotide Sequence(s) with Modified Derivatives (including Protector Groups)

Insertions of nucleotides that do not occur naturally (derived from natural nucleotides) are also considered modifications sufficient for the sequences to avoid falling under article 10 (IX). However, the presence of these nucleotides and the list of nucleotides of interest must be stated in the claims, in order to avoid the natural nucleotides of being indirectly included, resulting in a natural biological sequence.

The inclusion of these nucleotides in the sequences presented in patent applications is addressed in Rule PR #81/2013 issued by the BRPTO, as mentioned in item 2.2.2 of these Guidelines; and a list with examples of modified nucleotides and the acceptable acronyms for their definition is available in Table 2 of the Annex appended to this Rule (published in the Federal Official Gazette (DOU) – §1, #68 of April 10, 2013).

### 6.3.2 Fragments

Special attention must be given to the analysis of claims involving “fragments of sequences”, even though these sequences are included in the application. This remark is due to the fact that the definition of the “fragments” of a specific sequence includes all and any subdivision of the sequence presented, resulting in an undefined number of possible fragments that do not present any function/relational to the matter described in the application.

**Exemplo**

*An application presents a sequence SEQ ID NO: 1 (hypothetical): agctggttgcgtgctgcga. The claim refers to the “nucleic acid characterized by possessing the nucleotide sequence SEQ ID NO: 1 and fragments thereof”. In the manner in which it is described, this claim includes, for example, molecules such as: agct, actg, ctgg, ggtt, ggttc, cgactgt, and countless others, including many that have no function described or related with the invention.*
It is thus clear that the reference to the fragments of the specific sequence would not be acceptable in the claims, as the claimed subject matter lacks support and is not defined clearly and precisely as stipulated in article 25 of the Brazilian IP Statute. In these cases, the sufficiency of disclosure of the subject matter might be queried, pursuant to article 24 of the Brazilian IP Statute.

On the other hand, if the application describes that the fragments obtained from a specific sequence are useful for the purpose described in the invention, these fragments may be claimed, provided that the desired fragments are clearly identified in the claims (specifying the position of the initial and final nucleotides of such fragment) and that they are not natural.

6.3.3 Oligonucleotides (or Primers)

As they represent segments of complementary sequences to genes and/or natural mRNA, it is considered that primers form part of natural biological materials, and consequently claims addressing such primers falls under article 10 (IX) of the Brazilian IP Statute (note the possible exceptions in item 6.3.1).

6.3.3.1 Degenerated and Modified Oligonucleotides

Degenerated oligonucleotides generally consist of a mixture of oligonucleotides that might be used to amplify genes with sequences that are similar, but not identical (such as the amplification of orthologous genes in related species), or even unknown genes.

Attention must be given to the possibility that some of the resulting oligonucleotide(s) may be identical to a natural biological sequence (for example, to the sequence of the gene that it is intended to amplify), in this case falling under article 10 (IX). On the other hand, should it present modifications that result in a nucleotide sequence that differs from those found in nature, it will not be subject to article 10 (IX) (see item 6.3.1).

Moreover, as a mixture of oligonucleotides (for example, degenerated oligonucleotides, etc.) might not be clearly and precisely defined, claims related to this matter fail to comply with article 25 of the Brazilian IP Statute. Attention must also be paid to the description of this mixture in the specification (pursuant to article 24 of the Brazilian IP Statute).

On the other hand, in order to define the claimed subject matter clearly and precisely, a degenerated oligonucleotide might be characterized on the basis of a consensus sequence, varying in only one or a few pre-defined nucleotides. In these cases, claims for these degenerated oligonucleotides must mention the consensus sequence and the positions of the variable nucleotides.

6.3.4 Promoters

The promoter is the central regulation processor of a gene, as it contains the binding sites for RNA polymerases responsible for genetic transcription. By definition, this constitutes the 5’ regions of the gene. Processes resulting in transcriptional modulation are extremely complex and occur through an intricate network of interactions involving regulatory sequences (TATA box, CCAAT, box, etc.) and other elements locate further away from the transcription starting point (enhancer and silencer sequences).

In contrast to gene sequences with specific markers at the starting and ending points (for example: initiation codon,
polyadenylation site, etc.), a promoter sequence does not present such delimitations. Thus, experimental data must be presented proving that the isolated DNA sequence can result in the expression of gene sequences, meaning that it presents the promoter activity of interest.

There are intermediate cases in which a DNA sequence with promoter potential is isolated, sequenced and analyzed through bioinformatics technology for predicting possible regulatory motifs (CCAAT box, TATA box, CpG islands, etc.). Although of great value for preliminary studies, this in silico analysis is not sufficient to demonstrate that the identified sequence is in fact a promoter region, adequate functional trials are required for validation.

Nevertheless, as they consist of nucleotide sequences, the promoters must be represented by a sequence SEQ ID NO: X, as established in items 2.2.2 and 6.1.2.

Example 1:

Claim 1: DNA sequence characterized by being the SEQ ID NO: 1.

The above-mentioned sequence was isolated and presents promoter activity: this claim might not be accepted as it falls under article 10 (IX) of the Brazilian IP Statute.

However, in cases where the SEQ ID NO: 1 presents mutations, deletions and/or insertions, meaning that it has become different from the sequence as it is found in nature, examination of novelty, inventive step and industrial application for the invention is required. It must be noted that deletions may result in fragments that are considered as part of the natural material, and would thus, also be encompassed by article 10 (IX) (see items 6.3.2 and 6.3.3.1).

Example 2a:

Claim: Expression cassette characterized by comprising the promoter sequence SEQ ID NO: 1 linked operationally to a gene of interest and a terminator sequence.

Should sequence SEQ ID NO: 1 have been obtained from nature, and subsequently modified (through specific mutations, deletions and/or insertions), the above claim might be accepted, provided that the matter is deemed to be novel and inventive. Should the SEQ ID NO: 1 be as found in nature, the claim must be restructured in a manner that better specifies the cassette, through introducing the term “heterologous”, making it clear that this does not encompass protection for material falling under article 10 (IX) of the Brazilian IP Statute (see item 6.3.5).

Example 2b:

Claim: Expression cassette characterized by comprising the promoter sequence selected from group of the SEQ ID NO: 1 to 3 or its fragments and derivatives linked operationally to a heterologous gene of interest and a heterologous terminator sequence.

This type of claim must be analyzed by taking into consideration the above remarks on the example. Furthermore, with regard to the promoter sequence, this must be limited only to the sequences for which the promoter activity of interest has been demonstrated. Should promoter activity been demonstrated only for sequence SEQ ID NO: 1, for example, the claim must be limited to this sequence; furthermore the expression “or its fragments and derivatives” might not
be accepted, as the claimed subject matter is not properly supported or clearly and precisely defined in compliance with article 25 of the Brazilian IP Statute. In these cases the sufficiency of disclosure of the matter might be queried, pursuant to article 24 of the Brazilian IP Statute.

6.3.5 Vectors

A vector is a DNA molecule used as a vehicle for the transfer of exogenous genetic material to other cells. Normally, the DNA vectors present three characteristics: (i) they contain a sequence that corresponds to the origin of replication that allows their replication independent of the host chromosome; (ii) they contain a selection marker that allows the cells containing a vector to be identified easily; and (iii) they present single sites for one of more restriction enzymes. The cloning vector is intended to replicate an insert in a host cell. The expression vector contains an expression cassette that allows the insert to be expressed in the target cell in an induced or constitutive manner. The expression cassette contains regulatory sequences, such as promoter sequences and transcription terminator sequences.

With regard to sufficiency of disclosure as set forth in article 24 of the Brazilian IP Statute, the examiner must analyze the invention in question and the level of details needed for its replication, depending, for example, of whether the vector is the main invention or an accessory invention. Along these lines, some aspects must be noted in the specification:

- the drawing representing the map of the vector in question, highlighting the characteristics that are essential for its functioning, meaning the cleavage sites for the restriction enzymes, the appropriate restriction enzymes, the promoter used, the repression regions, the termination regions, the marker sequences or sequences that confer resistance to antibiotics, etc.;
- the sequence to be cloned and/or expressed in the form of SEQ ID NO: X must be present in the sequence listing, as set forth in the Rule(s) in force;
- should the preferred codons for the expression of the insert in a specific microorganism be essential to the invention, they may be included in the sequence listing; and
- the procedures and conditions for DNA/RNA manipulation, including the enzymes used (for example, endonucleases, polymerases, ligases, etc.), the cloning systems involved, and the transfection/transformation conditions of a host cell, among other usual techniques.

It must be stressed that when there is no other way of defining the vector in a replicable manner (sufficiency of disclosure – article 24 of the Brazilian IP Statute), the biological material must be filed (see item 2.2.1).

Some examples of claims designed to reflect everyday situations in which the vectors are recombinants are presented below. In other words, these examples do not encompass natural vectors found in bacteria, fungus and plants, especially in mitochondria and chloroplasts, as these are not considered to constitute inventions as set forth in article 10, item IX, of the Brazilian IP Statute.

Example: Vector as the main invention

Claim: Vector characterized by consisting of the filing number XXXX.

The main invention is a new and inventive vector that might be used for cloning and/or the expression of a gene of interest. In this case, the vector might be characterized in a claim by its filing number issued by an International Filing
Authority. Thus, the vector will be clearly and precisely defined as set forth in article 25 of the Brazilian IP Statute.

Example 23: Vector as the main invention

Claim: Vector containing the original sequence for replication, selection marker sequence and multiple cloning sites characterized by comprising the SEQ ID NO: X.

In this example, the vector structure is new and inventive due to the specific combination of the SEQ ID NO: X with the other elements common to vectors, such as the sequence of origin for replication, the selection marker sequence (for antibiotics, etc.) and the restriction enzyme sites. Consequently, the essential elements that distinguish this vector from others constituting the state of the art must be the only elements characterized by their respective SEQ ID NO: X, as the other components are known to a person skilled in the art. It must be stressed that, in this case, the SEQ ID NO: X does not correspond to the expression cassette.

Example 24: Vector as an inter-related invention

Claim: Vector characterized by comprising of the sequences defined by SEQ ID NO: X and SEQ ID NO: Y linked in an operative manner to the promoter and terminator heterologous sequences.

The invention describes two gene sequences involved in the transport of lysine that were isolated from Corynebacterium glutamicum. Sequence SEQ ID NO: X codes the lysine exporter protein (LysE), while sequence SEQ ID NO: Y codes the regulatory protein (LysG) of LysE. Although the SEQ ID NO: X and SEQ ID NO: Y are endogenous of the Corynebacterium host cell and, consequently, natural, they are flanked by heterologous genetic construction sequences present in the recombinant vector. Consequently, the vector is not encompassed by the provisions set forth in article 10 (IX) of the Brazilian IP Statute.

Example 25: Vector as an inter-related invention

Claim: Vector characterized by comprising a DNA construct that consists of the sequence defined by the SEQ ID NO: X operationally linked to the promoter and terminator transcription sequences.

The invention refers to a new gene sequence that is endowed with inventive step and is liable of cloning/expression in appropriate host cells.

In cases where the SEQ ID NO: X is identical to that found in nature, care must be taken to ensure that the constructions as a whole presents some heterologous sequence as a way of distinguishing it from the natural sequence. Consequently, if sequence SEQ ID NO: X is altered, the term “heterologous”, as used in example 24 is not necessary.

6.3.6 cDNA

cDNA molecules represent sequences produced through RNAs. In the case of cDNAs originating from messenger RNAs (mRNA), if the gene has introns, the cDNA will be different from the gene that encoded this mRNA, as the cDNA sequence will only have the sequence of exons. Thus, in these cases, it may not be considered that a cDNA molecule is the same as a natural molecule, and its patentability must be assessed on the basis of the requirements of novelty, inventive step and industrial application.
When the cDNA refers to molecules produced from mRNAs of genes that do not have introns, this cDNA will have the same constitution as the strand of DNA /gene that served as the template for the synthesis of this mRNA. Thus, in these cases, the cDNA is not considered to constitute an invention under article 10 (IX) of the Brazilian IP Statute.

In the cases in which a cDNA is obtained from other types of RNA (such as tRNA, snRNA, rRNA), it should be verified if they are identical to the natural DNA, in which case they would not be considered inventions under article 10 (IX).

Moreover, the simple sequencing of a cDNA without associating a function to it is not sufficient to ensure its industrial application (see item 1.1) and the support for the subject matter, failing to comply with articles 15 and 25 of the Brazilian IP Statute, respectively.

6.3.7 Expressed sequence tags - ESTs

The acronym EST refers to a partial sequence – or a fragment of a sequence – obtained from a cDNA (which is why it refers only to expressed sequences).

The simple sequencing of an EST is not sufficient to ensure industrial application and support for the subject matter, failing to comply with articles 15 and 25 of the Brazilian IP Statute, respectively.

Furthermore, in order to avoid falling under article 10 (IX), an analysis of this subject matter follows the same criteria used for cDNA; whereby it is necessary to know if the above-mentioned EST represents a sequence fragment from a single exon (in which case it would be considered as part of the natural biological material), or if it extends beyond the junction point between two different exons (in which case there is no natural equivalent, and it could, consequently, be considered to constitute an invention).

On the other hand, when referring to sequences derived from genes that do not have introns, any EST is considered to be a fragment of a natural biological sequence (see also item 6.3.2).

6.3.8 Open reading frames - ORFs

The acronym ORF refers to potential coding sequences generally obtained from DNAs sequencing. Furthermore, an ORF has a start codon (related to a methionine, for most organisms) and ends with a stop codon.

As this is a region of the genome, the ORF is deemed to constitute a natural product, thus not being considered to constitute an invention under article 10 (IX).

An ORF represents a candidate of a coding region of the genome, that does not necessarily result in a function or gene product. Thus, for a claim of the type “vector characterized by comprising the ORF present in SEQ ID NO: 1”, it is necessary to demonstrate the functionality of the product obtained through the expression of this ORF in order to comply with the industrial application requirement (article 15), as well as the clarity and accuracy of the claimed matter (article. 25).

6.3.9 RNAs

RNAs encoded by natural genes are also natural biological molecules and are, consequently, not considered to constitute inventions under article. 10 (IX) of the Brazilian IP Statute.
On the other hand, should they result from the expression of chimeric genes (such as genes constructed to express fusion proteins and / or others not found in nature), these RNA molecules may not be considered as natural biological material.

6.4 Amino Acid Sequences

For the purposes of definition, when analyzing patent applications, “proteins”, “peptides” and “polypeptides” must be defined on the basis of their linear amino acid sequence (primary structure), regardless of their size (total number of amino acid residues as set forth in Resolution PR #81/2013). Consequently, the mention of any of these terms (“proteins”, “peptides” or “polypeptides”) in these Guidelines shall, generally, refer to the “amino acid sequence” or the “protein sequence”.

6.4.1 How to characterized Amino Acid Sequences

As mentioned above, once the rules set forth in items 2.2.2 and 6.1 are complied with as a way of ensuring the clarity and precision of the claimed subject matter, the claim chart must refer to the proteins in question through the SEQ ID NO: in some cases, additionally, this may also correspond to their structural formulas. Sequences with up to 3 (three) amino acid residues must be represented throughout the entire application only by its sequence.

**Exemplo**26: Acceptable claims for amino acid sequences (provided that these sequences do not occur naturally).

Claim: Protein X is characterized by comprising the amino acid sequence as defined in SEQ ID NO: 1.

Claim: Polypeptide characterized by consisting of the amino acid sequence as defined in SEQ ID NO: 1.

Claim: Protein X characterized by consisting of the SEQ ID NO: 1 sequence.

**Example**27: Claims not acceptable for amino acid sequences.

Claim: Protein characterized by consisting of the amino acid sequence coded by sequence SEQ ID NO: 2 (nucleotide sequence).

*In this situation, a requirement must be issued, for the applicant to submit the amino acid sequence corresponding to the nucleotide sequence presented, without this constituting any addition of matter.*

Thus, claims will not be accepted with the protein sequences characterized only through their properties, such as three-dimensional structure, biological activity, name, chemical properties (PI, molecular weight, amino acid composition, etc.), as the only way of defining an amino acid sequence clearly, precisely and unmistakably is through the sequence itself.

Furthermore, attention must be given to item 6.2 of these Guidelines, which addresses biological sequence claims through the percentages of identity and / or similarity to a reference sequence.

It must be borne in mind that the use of the terms consists of or comprises results in differences in the scope of the claim (see the Examination Guidelines for Patent Applications, Block I).
Example 28: The specification of the application describes a mutated (not natural) protein that is characterized by consisting of the sequence SEQ ID NO: W. In this case, it would not be possible to accept a generic claim requesting protection for a mutated (not natural) protein that is characterized by comprising the sequence SEQ ID NO: W, as this would introduce the possibility of any extension in the carboxy and/or terminal amino regions of the protein that could result in alterations to its three-dimensional structure and/or alterations in function. Consequently, it would not be possible to state that any protein that comprises the SEQ ID NO: W sequence will function similarly to the protein that consists of the SEQ ID NO: W sequence, with such claim being rejected due to the absence of sufficiency of disclosure and support in the specification (articles 24 and 25 of the Brazilian IP Statute). Even if the specification discloses some possible extensions in the amino acid sequence of the protein, such examples would not be sufficient to support that any extension would attain the same results.

6.4.2 Homologous Proteins (Paralogous versus Orthologous)

Homologous proteins are proteins derived from a “common evolutionary ancestor”. They may be present in a single species, deriving from gene duplication, originating in what is called paralogous (equivalent proteins – with or without sequence alterations produced in the course of evolution – found in the same species). On the other hand, they may be found in different species that have a common ancestor, in this case, these proteins are called orthologous.

These definitions are important for assessing the inventive step of applications that describe and claim proteins similar to proteins whose functions are already known, differing only in terms of the organisms from which the protein is derived.

Example 29: A patent application describes protein B, isolated from a specific species. This protein B presents a sequence and activity very similar to another protein denominated A, previously described in the state of the art for a different species (A and B are, consequently, orthologous proteins). In these cases, the mere fact that protein B was isolated from a different organism does not necessarily make it inventive, compared to protein A. Thus, when assessing inventive step, it must be evaluated if protein B presents some unexpected characteristic compared to its orthologue A. Nevertheless, in this case, protein B would not be considered as constituting an invention under article 10 (IX).

Moreover, when applications involve “variants” or “modifications” of natural proteins, attention must be paid to the scope of article 10 (IX), as such modifications may result in another biological molecule that is proven to be natural, deriving merely from a species other than that described in the application.

Example 30: An application describes modifications in a bovine protein that make it appropriate for a specific use, and claims the modified protein. However, the protein resulting from the alterations introduced, such as substitutions, results in a sequence that is the same as the canine version of this protein, which is already known. In this case, even if not the same as the natural equivalent of the organism from which it was obtained, the claimed protein is the same as an orthologous protein—natural from another species—and is consequently also subject to article 10 (IX).

6.4.3 Protein Fragments

Similar to a protein, a protein fragment must be characterized by at least its amino acid sequence (see item 6.4.1). Thus, when a protein fragment is claimed and characterized only through its linear sequence, the examiner must conduct a search for the characterizing amino acid sequence. Should the sequence be found at the state of the art as part of a protein or peptide that is of natural origin, the claimed subject matter will fall under article 10 (IX) of the
Brazilian IP Statute, as it forms part of natural living being and/or biological materials found in nature.

When a peptide containing a few amino acids is claimed, it is likely that it will be found in some protein in nature, even with no known function in the protein or even in a context other than that of the material presented in the application under examination. Nevertheless, the claimed subject matter falls under the provisions set forth in article 10 (IX) of the Brazilian IP Statute, as this Statute does not stipulate any demarcation for the minimum size of a fragment to constitute part of a natural biological material. Thus, any part of natural living beings and biological materials (i.e. fragments) found in nature may not be considered as constituting inventions.

It is possible that a claimed fragment is identical to a part of an entire molecule found in nature. In these cases, even when the claimed fragment presents innovative activity, function, or chemical properties for the state of the art, as it constitutes part of a natural living being or a biological material found in nature, this does not constitute an invention under article 10 (IX) of the Brazilian IP Statute, thus not warranting any type of analysis of its novelty and inventive step.

It is important to note that the presence or inclusion of the term “recombinant” in a claim for natural molecules might not be accepted, as the resulting molecule would be indistinguishable from its natural counterpart, even if produced in a recombinant manner.

Thus, it is clear that any portion of a protein found in nature, regardless of the number of amino acids, must be considered as part of natural living beings and biological materials found in nature and will consequently not be deemed to constitute an invention under article 10 (IX) of the Brazilian IP Statute.

Example 31:

Claim: Peptide characterized by having the Ile-Leu-Arg sequence

Protection is claimed for a biologically active peptide obtained synthetically and with immuno-regulatory properties, consisting of three amino acids. After the search, it was shown that the sequence is contained in several natural proteins. The application argues that the peptide may be distinguished from the natural polypeptide in several aspects such as twisting, spacial conformation, aggregation and physical and chemical properties.

Although differences may exist in the physical and chemical properties of the claimed molecule, compared to natural polypeptides that comprise the same sequence, the claimed peptide presents a sequence of amino acids found in nature, which is why the material is not considered to constitute an invention under article 10 (IX) of the Brazilian IP Statute.

Example 32:

Claim: Protein characterized by having the SEQ ID NO: 1 in which positions 1 to 6 were deleted.

A cytokine of 76 amino acids when truncated at the sixth amino acid amino terminal, began to exhibit an antagonist activity for the entire cytokine, and thus might be used to manufacture medicines for treating diseases that require a cytokine antagonist.

Although human interference produced results in an innovative activity, this fact occurred merely through the deletion of part of the molecule, with the obtained sequence remaining identical to the 6-76 amino acid sequence found in the
entire natural molecule 1-76. According to article 10 (IX) of the Brazilian IP Statute, this analogue is not considered as constituting an invention as it consists of part of a natural molecule, and is thus not patentable.

6.4.4 Modifications to the Sequence

Modifications of protein sequences intended to distinguish them from natural sequences may be handled in different ways. In principle, any characteristic introduced in a sequence that has not been described as a natural occurrence is acceptable as a modification, whereby this does not fall under article 10 (IX) of the Brazilian IP Statute.

6.4.4.1 With Natural Amino Acids (Substitutions, Insertions or Deletions)

As mentioned above for modifications in general, modifications in biological sequences through the insertion of natural L-amino acids (in the middle or at the ends of the sequence) are considered as sufficient to avoid falling under article 10 (IX), provided that the resulting sequence formed is also not found in nature.

For the deletion of amino acids, the position of the deleted amino acid results in different situations to be taken into consideration. If located in a central part of the protein sequence, this modification is, in principle, sufficient to distinguish it from the natural molecule. However, if the deleted amino acids are contiguous and at the ends of the sequence, this falls under article 10 (IX), as the resulting contiguous sequence is identical to part of the natural sequence (see Example 32).

With regard to the substitution of amino acids by other natural amino acids, this modification is deemed sufficient for the sequence to avoid falling under article 10 (IX), provided that there is no description of any natural proteins in related species containing such substitution (see item 6.4.2 on orthologue proteins).

When analyzing proteins already described in the state of the art, a careful assessment of the inventive step of the modification is required (insertion, deletion or substitution), taking into account that some groups of amino acids present common properties. Thus, the inventiveness of these alterations in the protein sequence, generally, depends on the demonstration of an unexpected effect generated by the modification, compared to the state of the art.

6.4.4.2 With Non-natural Amino Acids (Including Protector Groups)

Insertions of amino acids that do not occur naturally (derived from natural amino acids) are also considered to constitute modifications that are sufficient for the protein sequences to avoid falling under article 10 (IX). However, for the purposes of clarity and precision, these amino acids must be appropriately identified in the claims, in order to result in the natural biological sequence.

The inclusion of these amino acids in sequences presented in patent applications is also addressed in Resolution PR #81/2013 issued by the BRPTO, as mentioned in item 2.2.2 of these Guidelines; and a list with examples of non-natural amino acids and the acronyms that are acceptable for their definition is available in Table 4 of the Annex appended to this Rule (published in the Federal Government Gazette (DOU) – §1, #68, April 10, 2013).

6.4.4.3 Groupings added to the terminal carboxy or amino

A protein sequence might also be altered through binding chemical groups to its ends, in order to allow it to be
anchored to a specific surface or structure, with increased protein activity, bio-availability modulation and / or circulating half life, etc.

Once again, attention must be paid to the manner in which such molecule is claimed, in order to ensure the presence of the chemical group in the molecule, as it is this group that will distinguish it from its natural equivalent. Fmoc, t-boc, other chemical groups, prosthetic groups, lipids, carbohydrates, iron, calcium and heme are examples of groups that, when added to proteins, may possibly distinguish them from their natural counterparts.

### 6.4.5 Fusion Proteins

By definition, these are proteins created by the union (fusion) of the parts of two or more different protein sequences. Thus, a fusion protein addressed by a patent application is formed by at least a “functional” portion that accounts for the property related to the invention.

Consequently, for the purposes of definition and in compliance with article 25, it is important to stress that, for a fusion protein, all the functional portions in the final protein must be described in the application.

#### 6.4.5.1 Of Natural Occurrence

Rare cases of naturally expressed fusion proteins are noted in some types of cancer, due to chromosome translocation, which may result in the fusion of different genes, such as gag-onc, Bcr-abl, and Tpr-met fusion proteins.

Once the occurrence of a natural identical structure has been proven, consonant with the provisions set forth in item 4.2.1 (for example, Bcr-abl, with a portion 1-50 of Bcr fused to the abl 13-78 portion), these proteins may not be considered to constitute invention under article 10 (IX) of the Brazilian IP Statute.

#### 6.4.5.2 How to Characterize

In general, when defining fusion proteins, the rules established for any other protein sequences are valid (see item 6.4.1). Thus, references to homology, similarity or identity percentages are not accepted, and the proteins must be referred through at least by one of their amino acid sequences or by the SEQ ID NO: corresponding to the functional portion.

#### 6.4.5.3 Entire SEQ ID

When the polypeptide sequence described in the patent application is claimed in the form of a fusion protein, this must always be referred through at least its amino acid sequence or the corresponding SEQ ID NO:, in order to define in a clear and precise manner the claimed subject matter related to the invention.

When several peptides are related to the property described in the invention, and they are all present in the claimed fusion protein, all these peptides must be referred through at least their amino acid sequence or the corresponding SEQ ID NO:.

Special attention must be paid to cases in which the “fusion” protein is in fact formed by fragments of a same protein that occur naturally: depending on the manner in which it is claimed, the final protein produced (fusion protein) may turn out to be the same as the natural molecule.
Example 33:

Claim: Fusion protein characterized by the fact that it comprises:

a. a first polypeptide that consists of the amino acid sequence 41-56 of SEQ ID NO: 2;
b. a first spacer of 6-27 amino acids;
c. a second polypeptide that consists of the 69-84 amino acid sequence of SEQ ID NO: 2;
d. a second spacer of 5-11 amino acid; and

e. a third polypeptide that consists of the amino acid sequence 92-105 of SEQ ID NO: 2.

In this claim, as there is no definition of the spacers of interest, mentioning ranges compatible with the interval between the defined sequences, the scope of the resulting “fusion” protein encompasses in its scope the protein itself, the sequence of which is described in sequence SEQ ID NO: 2, which occurs naturally, falling under article 10 (IX).

6.4.5.4 Definition of only one of the Sequences in the Fusion Protein

When the protein of interest is fused with another polypeptide that will serve merely as a “lable/reporter”, this reporter might be defined through its amino acid sequence or the corresponding SEQ ID NO:, as established previously for any polypeptides. However, if such “reporter” polypeptide is widely known at the state of the art, reference to it might, optionally, be made through its acronym, such as GFP (green fluorescent protein), GST (glutatione S-transferase), CAT, c-Myc, FLAG molecules, among others.

An application might, eventually, present the type of situation in which the inventive characteristic of the fusion protein is found only in the presence of the protein described in the application - which might even be the reporter portion - and this might be fused to several others.

Example 34:

The application describes a polypeptide X that alone does not have any surprising activity, but that can enhance the immunological response to antigens that are fused to it. In the claim chart a “fusion protein characterized by consisting in protein X (defined by its SEQ ID NO:) bound to an antigen” is claimed.

In this case, attention must be paid to the clarity and precision of the manner in which the fusion protein is claimed, as the antigen that is fused to it is not defined in the claim, and the decision to be taken must consider the information available in the specification.

Situation 1: The specification presents examples of protein X fused with several different unrelated antigens and demonstrates the undeniable efficacy of all the resulting proteins for the proposed purpose, with no indication that another antigen would not function in the same manner. In this case, it is not necessary to require the application to list all the possible antigens that could be used in the fusion protein, and it is considered that the claim is acceptable in the manner in which it is worded above.

Situation 2: The application presents examples of protein X fused with various different antigens, unrelated, but the results demonstrated are not consistent, showing that the fusion protein is efficacious for some antigens and not for others. In this case, the application does not provide sufficiency of disclosure and support in compliance with articles 24
and 25 as required to ground that the fusion protein functions with any antigen (it may include antigens for which there is no evidence that they function as described). Consequently, the claim chart must be limited to the matter described and for which support is presented in the application in accordance with articles 24 and 25 of the Brazilian IP Statute, i.e., the claims must specify which are the antigens of interest present in the claimed fusion protein.

6.4.6 Antibodies

Antibodies are plasma proteins that bind specifically to known substances such as antigens, and include polyclonals and monoclonals; consequently, they must be analyzed as proteins, including in regards to the provisions set forth in article 10 (IX) (see item 6.4 and its sub-items).

Polyclonal antibodies are derived from different B cell lines. They are a mixture of immunoglobulin molecules secreted against a specific antigen, with each recognizing a different epitope. These antibodies are biological products isolated from nature and, thus, are not considered to constitute inventions under the provisions set forth in article 10 (IX) of the Brazilian IP Statute. It is worthwhile stressing that the isolation of a specific antibody from this pool of antibodies does not exclude this molecule from the condition set forth in article 10 (IX).

Monoclonal antibodies are antibodies with a single specificity, meaning that they are specific for a single epitope in an antigen. Through human intervention, a monoclonal antibody can be obtained by different techniques, such as hybridoma (see item 6.4.6.2) or genetic engineering techniques.

When obtained through a hybridoma and characterized as such, a monoclonal antibody might not be considered natural and would, consequently, not be subject to the provisions set forth in article 10 (IX). It must be stressed that, in this situation, this monoclonal antibody might additionally be defined by its specific sequence (SEQ ID NO:). For monoclonal antibodies obtained through genetic engineering, as they are defined by their sequence they may be accepted, provided that they are not subject to the provisions set forth in article 10 (IX) (see item 4.2.1).

Example: Wording of claim for antibody liable of patent protection.

Claim: Monoclonal antibody against protein X characterized by the fact that it is produced by the hybridoma HHH, filed under number YYYY.

Example: Antibody claims that are not acceptable.

Claim 1: Antibodies characterized by the fact that they are specific for protein X.

As they do not clearly and precisely define the antibodies that are being claimed, such claims cannot be accepted as they contravene article 25 of the Brazilian IP Statute, and may encompass natural molecules, including those addressed in article 10 (IX).

Claim 2: Human monoclonal antibody characterized by the fact that it recognizes protein X and that it has a 2x10-9 M affinity.

Claim 3: Monoclonal antibody and its fragments characterized by the fact that it can bind to protein X.
As they fail to define the antibodies clearly and precisely, not stating which fragments are being claimed, these claims may not be accepted, as they contravene article 25 of the Brazilian IP Statute.

6.4.6.1 Process of Obtaining Antibodies

The production process for a polyclonal antibody that consists only of the exposure of an animal to an antigen, followed by purification, is considered a natural biological process, and is thus not deemed to constitute an invention, falling under article 10 (IX). However, in some cases, if any non-trivial technical stage involving the determination of the epitope or modification of the antigen in order to elicit the immunological response, it is felt that there is significant human intervention, given that there is a direct action on the molecule, with a decisive impact on the final results. In these cases, such processes are liable of patent protection.

In counterpart, due to human intervention, the production process for monoclonal antibodies is not considered to be a natural biological process, whether this involves obtaining it through a hybridoma or through genetic engineering techniques.

With regard to the characterization of the process for obtaining antibodies, attention must be paid to the need to define the stages of the process (see item 4.2.1.2).

6.4.6.2 Hybridomas

Hybridomas are the result of a fusion of two cell types, a myeloma and a B lymphocyte, and produce antibodies. They present characteristics that cannot be attained by these cell types under normal conditions, being the outcome of direct human intervention. As addressed in the understanding adopted by this Institute, from the technical point of view, a hybridoma is considered to constitute a transgenic microorganism, and such matter is thus patentable, as it does not fall under articles 10 and 18 of the Brazilian IP Statute.

At the same time, as this involves biological material that is essential for the practical embodiment of the purpose of the patent application, and that cannot be characterized in a clear and precise manner in the specification, in order to comply with the sole ¶ of article 24 of the Brazilian IP Statute, it is essential the filling of the hybridoma by the filing date of the patent application or its priority date, with the presentation of the filing number in the patent application (see item 2.2.1).

6.4.6.3 Chimeric/Humanized Antibodies

Monoclonal antibodies produced from mice, rabbits, etc. when used as therapeutic agents in human beings, are recognized as foreign proteins by the immune system of the human host. The advent of chimeric/humanized antibodies is a mechanism used to surmount this therapeutic obstacle.

The technology for the production of a humanized antibody differs from the production of a monoclonal antibody, because it does not depend on cultivating the hybrid cell, but requires the immunoglobulin sequence to be obtained (human Fc portion and variable portion of the non-human Fab fragment). These sequences are merged and placed in an expression vector for subsequent cultivation of the transfected host cell and subsequent purification stages. Due to this difference in the production route, the characterization of the humanized antibody
requires the presentation of a SEQ ID NO: X containing the amino acid sequence of the variable portion of the
tool and the definition of the other elements (Fc portion).

**Example**: Wording of antibody claims liable of patent protection.

Claim: Humanized antibody against α-actin characterized by comprising the variable murine region consisting of
the sequence SEQ ID NO: X and regions constants in the human γ chain.

Claim: Humanized antibody against γ-actin characterized by comprising the complementarity determining murine
regions (CDR1; CDR2; CDR3) that consist of the SEQ ID NO: X, SEQ ID NO: Y and SEQ ID NO: Z in the light chain and
sequence SEQ ID NO: A, SEQ ID NO: B and SEQ ID NO: C in the heavy chain and regions of the human γ chain.

### 6.4.6.4 Antibody Fragments

The antibody molecule might be cleaved generating different fragments with distinct functions. Should the
fragments originate from antibodies found in nature, or form part of other natural proteins, they are not liable of
patent protection under article 10 (IX) of the Brazilian IP Statute (see item 6.4.3).

Modifications to antibody fragments may also be liable of patent protection, as is the case with single chain
variables fragments (ScFv). The Fv fragments are not covalently bound, therefore the VH and VL domain
heterodimers can be easily dissociated. However, Fv fragments may be constructed in a manner whereby they
do not dissociate, meaning that the VH and VL domains may be linked by a connector, creating a single chain Fv
fragment. Despite being an antibody fragment, this construction does not fall under article 10 (IX) of the Brazilian IP
Statute, as these fragments are not found in nature linked by the connector.

### 7. Animals, Plants, their Parts and Obtainment Processes

#### 7.1 Animals, Plants and their Parts

If natural or isolated, they are not considered to constitute inventions, under article 10 (IX). When resulting from
genetic manipulation by human beings, they are not liable of patent under article 18 (III).

#### 7.1.1 Products and Processes involving Stem Cells

Stem cells are undifferentiated cells (totipotent, pluripotent or progenitor) that can be stimulated to differentiate
into the various tissues that constitute the human body.

According to these Guidelines, products and processes involving stem cells refer exclusively to pluripotent or
progenitor stem cells. These cells may be directly obtained from various tissues in the adult organism (such as
bone marrow or adipose tissue, for example), or even from the umbilical cord, or they may be obtained through the
dedifferentiation of a differentiated adult cell (as with induced pluripotent stem cells - IPS).

Alternatively, they may be obtained from the internal mass of blastocysts taken from human embryos produced
through in vitro fertilization, pursuant to the provisions of article 5 of the Biosecurity Statute (Statute #11,105/2005),
dated May 11, 2005.
According to the Brazilian IP Statute, cells obtained directly from an animal or with some modification to its genes, are not patentable under the provisions set forth in article 10 (IX) or 18 (III), respectively. However, compositions containing these cells or processes for obtaining stem cells and the application (use) thereof may be considered as patentable, provided that they do not imply or include the therapeutic and/or surgical method (article 10 (VIII)), and provided that they do not fall under the provisions set forth in article 18 (I) of the Brazilian IP Statute.

For example, the following products and processes involving stem cells could be considered as liable of patent protection:

- Compositions containing cells and other ingredients (assorted implants containing cells, cell and matrix formulations, growth factors and cells...).
- Composition containing mixtures of different types of stem cells.
- Purification, preparation, conditioning, differentiation and dedifferentiation processes, or any stem cells processing that is performed in vitro.
- Uses of cells for preparing medications to treat disease X.
- Uses of cells for preparing implants to treat disease X.
- Uses of cells for preparing compositions to diagnose disease X.
- Diagnostic processes that include stages using stem cells or synthetic tissues, provided that they are performed in vitro.
- Drug tests that include stages using stem cells or synthetic tissues provided that they are performed in vitro.
- Stem cells cultivation processes.
- Conditioned culture media obtained during stem cultivation.

7.2 Transgenic Plants, their Parts and Obtainment Processes

These are plants whose genomes have been modified through the introduction of a DNA manipulated by recombinant DNA techniques, and whose modification would not occur under natural crossing or recombination conditions.

Transgenic plants and their parts (for example, transgenic cell, transgenic tissue and transgenic organ) are not considered as constituting patentable subject matter under article 18 (III and Sole ¶) of the Brazilian IP Statute.

Even if the process of obtaining transgenic plants is patentable, it is important to stress that the intermediate and/or final product resulting from this process, meaning the transgenic plant and/or the parts of this plant constitute materials whose patentability is expressly forbidden under article 18 (III and Sole ¶) of the Brazilian IP Statute. However, there are no constraints on patenting the processes used for obtaining these plants.

Examples of Claims Liable of Patent Protection

Production method for transgenic plant characterized by comprising the following stages:

a. obtaining a plant explant;
b. exposure of the explant to a culture of Agrobacterium tumefaciens that contains the vector defined in claim X (duly described with a selection gene, a heterologue gene and the promoter sequence(s);
c. cultivation of the explant in a medium with the specific cultivation conditions required for vegetal tissue; and
Method for producing a transgenic dicotyledonous plant, characterized by comprising:

a. transform plant cells using an Agrobacterium transformation vector that comprises a chimeric construct of gene Y;

b. obtain a transformed plant cell; and

c. regenerate a genetically modified plant from the transformed plant cell.

7.3 Process of Plant Obtention Through Crossing

Article 10 (IX) of the Brazilian IP Statute establishes that natural biological processes are not considered to constitute inventions, and consequently excludes the patenting of natural biological processes, including those used to produce plants.

"Natural biological processes" is taken to mean all processes that do not use technical procedures to obtain biological products or that, even if using a technical procedure, could occur in nature without human intervention, consisting entirely of natural phenomena. Along these lines, biological processes shall be considered as not natural when direct human intervention is required in the gene composition, and the effect is permanent.

Thus, processes involving the crossing of genetically modified plants through direct human intervention are liable of patent protection.

Example 38: Non-transgenic parentals.

Claim 1: Methods for producing a plant X characterized by comprising the following stages:

a. selection of a plant X homozygote for gene A;

b. selection of a plant X homozygote for gene B; and

c. crossing the selected plants at stages (a) and (b) in order to produce a hybrid plant.

Conventional methods of producing plants based on stages of selection, crossing and propagation, are considered to be natural biological processes, falling under article 10 (IX). In these cases, human intervention through the selection and induction of specific crossings is not essential for the process to occur, but merely speeds up or limits what would occur in nature.

Example 39: Non-transgenic parentals.

Claim 1: Method for producing a plant X with high levels of compounds W, characterized by comprising the following stages:

a. identifying gene markers linked to high levels of W;

b. selecting individuals through the markers identified in stage (a); and

c. crossing the selected individuals in stage (b).
Conventional plant production methods based on stages of selection, crossing and propagation in which human intervention consists of merely providing additional technical procedures to streamline or steer the process propagation - in this case, the identification of gene markers - are considered as natural biological processes falling under article 10 (IX). In these cases, human intervention is not decisive for obtaining the final result, merely speeding up or limiting what would occur naturally.

**Example:** Transgenic parentals.

Claim 1: Method of producing hybrid seeds characterized by comprising the crossing of a herbicide resistant plant with a plant endowed with enhanced nutritional value comprising in its genome a heterologue gene coding for a modified albumin.

Claim 2: Method of introducing a characteristic of resistance to a herbicide in a plant endowed with enhanced nutritional value characterized by comprising the following stages:

- a. crossing a plant resistant to at least one herbicide with a plant whose genome encompasses a heterologue gene coding a modified albumin;
- b. developing background populations;
- c. assessing plants obtained individually; and
- d. selecting plants with enhanced nutritional value encompassing the characteristic of resistance to herbicides.

*This process involves a technical stage that is essential for obtaining the plant that does not occur in nature, and consequently does not fall under article 10 (IX).*

### 8. Patent Applications involving Genetic Heritage Components

Patent applications of inventions for a process or product obtained through samples of components in the Brazilian genetic heritage, filed as of June 30, 2000, must comply with the standards established in Provisional Measure (MP) #2186-16/01 promulgated on August 23, 2001, as well as Rule #34 by CGEN on February 12, 2009 and Rule PR #69/2013, issued by the BRPTO on March 18, 2013.

Provisional Measure (MP) #2186-16/01 rules, among other matters, on the assets, rights and obligations arising from access to a component of Brazil's genetic heritage found in Brazilian territory, on the mainland and in the exclusive economic zone for the purposes of scientific research, technological development or bioprospecting, as well as access to traditional knowledge associated with the genetic heritage that is relevant for conserving biodiversity, the integrity of Brazil's genetic heritage and the use of its components (article 1, items I and II).

In its article 31, this Provisional Measure states that the granting of industrial property rights for a process or product obtained through a sample of a component in the genetic heritage is conditional on compliance with the Provisional Measure (MP), with the applicant necessarily stating the origin of this genetic material and the associated traditional knowledge, when applicable.

The standards established in Provisional Measure (MP) #2186-16/01 must be complied with in patent applications involving Brazil's genetic heritage. As non-exhaustive examples, organisms may be mentioned (plants, animals, fungus, bacteria, archeae, etc.), parts of organisms (leaves, claws, skin, mucus, blood, roots, extracts, organs, oils,
poisons, fangs, etc.), molecules isolated from organism (DNA, RNA, proteins, sugars, lipids, etc.), and their synthetic correspondent, as well as compositions and processes containing any one of the above-mentioned items. Pursuant to article 3, this Provisional Measure (MP) is not applicable to human genetic heritage.

The applicant must always provide information on the origin of the material through the petitions established in Rule PR #69/2013 issued by the BRPTO: a petition requesting information on access or a petition to declare that the application filed does not involve access as addressed in Provisional Measure (MP) #2186-16/01. Pursuant to Rule #35/2011 issued by the CGEN, for regularization purposes, the registered request for authorization to access the genetic resource may be accepted, with the allowance of the patent application being conditional on presentation of the definitive authorization to access the genetic resource.

9. References


The TRIPS Agreement and Policy Options”. Third World Network, Malaysia.


INPI – “Diretrizes para o exame de pedidos de patente nas áreas de biotecnologia e farmacêutica depositados após 31/12/1994”.


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

This text aims to clarify the utility model applications concepts, as well as establish the procedures related to the examination, in order to standardize and streamline the examination.

This Utility Model Patent Examination Guideline forms an integral part of the Patent Application Examination Guidelines, addressing matters related only to this topic. The other topics inherent to the examination are listed and discussed in the Patent of Invention Application Guidelines.

It is stressed that this guideline seeks to guide the procedures in general, with specific and/or exceptional cases being addressed in a coherent manner by the examiner.

2. Differences between Utility Model Patents and the Patent of Invention

The Brazilian Industrial Property Statute - Brazilian IP Statute - Statute #9,279 on May 14, 1996 defines the Utility Model as: Article 9. An object of practical use, or part thereof, is patentable as a Utility Model, when it is susceptible of industrial application presents a new shape or arrangement and involves an inventive act, that results in a functional improvement in its use or manufacture.

The difference between a Patent of Invention and a Utility Model Patent is of the utmost importance for anyone wishing to protect their creation. In principle, the inventor may request protection through a Utility Model Patent or a Patent of Invention.

However, the inventor must reflect on the best type of protection, and may better identify the kind (Invention or Utility Model) for his creation shape or arrangement introduced into the object for practical use, or part thereof, conferring a functional improvement on an object known at the state of the art, for its use or manufacture.

The utility model is a creation of something resulting from the intellectual capability of its creator, referring to an object for practical use or part thereof. This object must be three-dimensional (such as instruments, utensils and tools), presenting a new shape or arrangement that involves an inventive act and results in a functional improvement in its use or manufacture. It must be susceptible of industrial application. Systems, processes, procedures or methods for obtaining a product are not included in this type of protection.

In turn, the Invention is a creation of something resulting from the intellectual capability of its creator, representing a new solution to an existing problem in a specific technological area, endowed with inventive step. Inventions may be related to industrial products (compounds, compositions, objects, equipment, devices, etc.) and to industrial activities (processes, methods, etc).

Patents of Invention are intended to protect technical creations that solve problems in a specific technological area. While Utility Model Patents are objects that do not pursue a specific technical effect (in which case they would constitute an invention per se), they are intended to enhance the use of the object and may result in greater efficiency or convenience in its use.

We may have creations of shape or arrangements classified as a Patent of Invention or a Utility Model. What determines the correct definition of the correct kind is an assessment of whether we are looking at an enhanced
effect or functionality which would be protected as a Utility Model Patent – or a new technical functional effect – which would be protected by a Patent of Invention.

3. Utility Model Application Content

The Utility Model Application Patent must Contain:

a. Title
b. Specification
c. Claim Chart
d. Summary

Only the Utility Model Patent Claim Chart presents differences compared to the Patent of Invention. Remarks on the title specification, drawings and summary are set forth in the Patent of Invention Examination Guidelines. However, it must be stressed that drawings are essential for Utility Model Patent Applications, in order to ensure a perfect understanding of the claimed object.

3.1 Formulation of Claims

A claim must be formulated in the following manner:

• initial part, corresponding to the title;
• when necessary, a preamble containing the characteristics already comprised by the state of the art;
• necessarily, the expression “characterized by”, followed by a descriptive part containing the new shape or arrangement introduced, with all the elements that constitute it, as well as their positions and interconnections in terms of the entire set.

This separation between known and new elements is designed to facilitate this distinction, as it does not alter the range or scope of the claim, which shall always be determined on the basis of the sum of the characteristics set forth in the preamble and in the descriptive part.

Each claim must define in a clear, precise and in a positive manner, the technical characteristics to be protected thereby, avoiding expressions that result in a lack of definition for the claim.

The condition that the claims must be clear is applicable to individual claims as well as the Claim Chart as a whole. The clarity of the claims is of vital importance, as they define the object matter of protection. Thus, the meaning of the terms used in the claims must be clear to a person skilled in the art based on the wording of the claim, and grounded on the specification and drawings.

3.2 Independent Claims

Each application must contain a single, independent claim that describes the Model fully defining all the characteristics of shape or arrangement introduced that are essential for achieving the functional improvement.

3.3 Dependent Claims

Dependent claims shall be accepted only when:
they refer to a complementary element for optional use that does not alter or modify the use and functioning conditions of the object;
they refer to a variation in the shape or detail related to the elements constituting the components of the Model, defined in the first claim, and that do not alter the Model unit (technical, functional and corporeal unit of the object) and its functioning;
they refer to the object in its three-dimensional shape in cases where the final configuration is secondary and derives from the assembly of a planned initial structure characterized in the first claim.

4. Procedures Related to the Examination of Utility Model Patent Applications

4.1 Classification

The rules for classifying Utility Model Patents are the same as those applicable to Patents of Invention, as set forth in the Strasbourg Agreement. Utility Models shall be classified according to their functions and applications, should the specification indicate a particular application for the claimed object.

In Utility Models, we have two clear concepts that should not be confused. One of these concepts addresses the function of the object, its functionality which is what the law refers to when addressing a functional improvement; the other concept is its use or application.

For example, we might have a box for packaging products. This is its function (described through verbs) “pack”.

However, we may have several applications or assorted technical fields, ranging from packing oranges to cans of paint. The two concepts are not to be confused.

4.2 Search

For the Utility Model, the search for prior art document must always take into account the classification of the claimed object. It is important to state that the search for prior art document for a Utility Model Patent Application must always be conducted among objects with the same function. However, the examiner must set up the search field in compliance with the function and application of the object, as objects may be found in both of them with the same functionality as the proposal in the application under examination.

For example, a request object designed for packaging liquid products. During the search, an identical type of packaging was found for packing paste and/or granulated products. This prior art document must be taken into consideration in the analysis, as both objects have an identical function (packaging), regardless of their contents.

4.3 Analysis of Patentability Requirements

4.3.1 Industrial Application

Article 15. The Invention and the Utility Model are deemed to be susceptible of industrial application when they can be used or produced by any type of industry.

Article 15 is quite clear when specifying that the Utility Model is deemed to be susceptible of industrial application
when its object is liable or able to be manufactured or used by any type/kind of industry, including agricultural, extract and extractivist industries, as well as natural or manufactured products.

4.3.2 **New Shape or Arrangement (Novelty)**

**Article 11.** The Invention and the Utility Model are deemed to be new when they are not included in the state of the art.  

1. The state of the art consists of everything accessible to the public prior to the Patent Application filing date, through written or spoken description, use or any other means, in Brazil or elsewhere in the world, except for the provisions set forth in Articles 12, 16 and 17.  
2. In order to ascertain novelty, the complete content of the application filed in Brazil and not yet published shall be deemed to constitute the state of the art as from the filing date thereof, or the claimed priority filing date, provided that it is published, even if subsequently.  
3. The provisions set forth in the previous ¶ shall be valid for an international Patent Application filed under a treaty or convention in effect in Brazil, provided that this can be processed locally.

The new shape or arrangement, meaning the novelty, lies in the technical structural characteristics of the object that are not yet found in the state of the art, regardless of its function or field of application. The state of the art consists of all information available to the public prior to filing the Patent Application.

In conceptual terms, the novelty of the Utility Model is the same as that of an Invention, and must be ascertained through the sole document principle. The sole document principle refers to the fact that for any prior art document to inhibitive, it must present in full all the elements of the technical solution for which novelty is claimed.

4.3.3 **Inventive Act**

**Article 14.** The Utility Model shall be taken to involve an inventive act when it does not derive in a common or usual manner from the state of the art, for a person skilled in.

The new shape or arrangement is the outcome of the inventive act. For an object already found at the state of the art, the inventive act characterizes an uncommon or not ordinary difference between these two objects, that is proposed by the application and that is anticipated by the state of the art. In other words, the difference must not be routine, habitual, normal, trivial or ordinary, for a person skilled in the art.

The definition of a person skilled in the art is comprehensive. A person skilled in the art might be someone with a fair knowledge of the state of the art at the time the application was filed, at the technical scientific level, and / or someone with practical operating knowledge of the object. It is considered that such persons have the means and ability to work and to execute routine experimentation, which is usual in the technical field in question.

When assessing the inventive act, a single prior art document shall preferably be used. In some situations in which the construction details of the object are found in a supplementary manner in some other prior art document, this may be used against the inventive act addressed by the application under examination, provided that this document presents construction details of the object.

**Example:** A Utility Model Patent Application was filed for a PET bottle cap, with weakening points (A), internal threads and a ring linked to the upper part of the cap by the weakening points, as shown in figure 1. The searches
found a document presenting a cap for liquids that had weakening lines (B), internal threads and a ring slightly larger than the PET bottle cap ring. In this case, the PET bottle cap is not identical to the cap found at the state of the art. However, weakening line B has the same function as weakening points (A), meaning that it separates the upper part of the cap from the ring and they both have the function of indicating any tampering with the receptacle (opened), which suggests the absence of an inventive act for the cap shown in Figure 1.

4.3.4 Functional Improvement

The term “functional enhancement” appears in Article 9 of the Brazilian IP Statute:

Article 9. An object for practical use or part thereof is patentable as a Utility Model when susceptible of industrial application and presents a new shape or arrangement, involving an inventive act that results in a functional improvement for its use or manufacture.

Even if endowed with an inventive act, a new object is not patentable if it not encompass a functional improvement. Functional enhancement is related to the use of the object in a more practical, convenient and/or efficient manner for the use and/or manufacture thereof. Consequently, the functional enhancement must be declared by the applicant.

Article 9 of the Brazilian IP Statute requires the Utility Model Patent to be endowed with an inventive act that results in the functional enhancement of the use or manufacture of the object. Thus, in addition to this functional enhancement, the presence of a minimum level of inventiveness is also necessary, the inventive act. If we assume that inventive act and functional enhancement have the same meaning, this would imply that patents could be awarded for outcomes, as a functional enhancement of an object might be deemed to be common or ordinary for a person skilled in the art.

In other words, we must understand that the concepts of functional enhancement and inventive act are related but distinct concepts, whereby a trivial or ordinary variation that introduces a functional enhancement would not be protected by Utility Model due to the lack of an inventive act, thus not protecting the outcome.

4.3.5 Distinct, Additional Elements and Constructive or Configurative Variants

The terms “constructive variant” and “additional and distinct elements” appear in the Brazilian IP Statute in the following Article:
Article 23. The Utility Model Patent Application must refer to a single main model which may include a plurality of distinct, additional elements or structural or configurative elements, provided that the technical, functional and corporeal unity of the object is maintained.

A constructive variant of a patentable object as a Utility Model is a modification to the part of the object that performs the main function of the object, meaning that it is a variation in the core element in question, although without altering the technical and functional unit.

Example: Figure 3 presents a screwdriver with a square tip and Figure 4 shows a screwdriver with a domed tip. The domed tip of the screwdriver is a constructive variant of this object. The main element of the screwdriver, its tip, is altered in its shape, but its technical and functional unity is maintained, which is to turn a screw.

Figure 3 - Screwdriver
Figure 4 - Larger screwdriver with domed tip

The additional complementary element is another object that is secondary to the main object. For the above-mentioned screwdriver, a cover for the tip that is designed to protect it, or a clip on the handle for holding the screwdriver in a pocket are examples of additional complementary elements.

Both constructive variant and complementary elements, provided that they do not modify the conditions for the use and functioning of the object, are characteristics that must be addressed in dependent claims presented in the same application.

An example of modification to the technical functional unit of the above screwdriver is, for example, an alteration to its handle in order to prevent it from slipping out of the hands. This new characteristic was not addressed by the first model, and must consequently form the subject of another application.
Brazilian PTO Rule #151/2015 on fast-track patent examination

This Rule establishes prioritized examination procedures on patent applications due to applicant's age or severe disease, due to the undue use of the invention, or in situations where the patent is required for grants of financial subsidies for invention release into market.
Through the powers invested in him by internal regulations, and considering the provisions of both Statute #9,279 of May 14, 1996 (Brazilian IP Statute) and article 159 of Administrative Rule #149 of May 15, 2013, THE PRESIDENT OF THE BRAZILIAN PATENT AND TRADEMARK OFFICE (BRPTO) DETERMINES:

**Article 1.** This Rule provides for the prioritized examination of patent applications due to the applicant’s age or severe disease, as well as for undue use of invention or when the patent is required in order to obtain promotion funds under the BRPTO.

**Article 2.** Applicants that may request prioritized examination of patent applications include:

I. the applicant him/herself, in cases where:
   - the applicant is proven to be at least 60 years-old;
   - third parties reproduce the subject-matter of the patent application without the applicant’s previous consent;
   - promotion funds from promotion agencies or official national credit institutions are not obtained unless patent is granted, when such funds are cleared as economic subsidy, financing or corporate stake, or otherwise arise from mutual investment funds that will exploit the relevant product or process; or
   - the applicant is a person with functional or mental disabilities, or has a severe disease, defined under both article 69-A, §§ II and IV of Statute #9,784 of January 29, 1999 and article 4 of Executive Order #3,298 of December 20, 1999.

II. third parties, when the applicant proves that such third parties reproduce the subject-matter of the patent application without the applicant’s prior consent.

III. third parties that prove they hold the relevant patent application, patent, or technology pertaining to that patent application.

**Article 3.** The only prioritized examinations that will be completed ex officio entail patent applications having a subject-matter provided for by Federal Executive Branch enactment declaring that the relevant patent calls for national emergency or public interest, under Article 2, §§ 1 and 2 of Executive Order #3,201 of October 6, 1999.

**Article 4.** The relevant person must use the free patent application request for prioritized examination.

**Article 5.** The below documents will accompany the patent application request for prioritized examination:

I. when the request is made under above article 2, §1, line a, a copy of ID card or birth certificate;

II. when the request is made under above article 2, §1, line b:
   - proof that the third parties are reproducing the subject-matter of the patent application without the applicant’s consent; and
   - a copy of the extrajudicial notice delivered to the party charged with undue reproduction of the subject-matter of the patent application, including proof of receipt, issued by the relevant applicant or duly designated attorney. This extrajudicial notice must expressly refer to the patent application number, the applicant name and the allegedly undue act.

III. when the request is made under above article 2, §1, line c:
   - a copy of request of funds for development of patent subject-matter made to the promotion agency or credit institute; and a copy of the instrument setting out that funds will not be cleared unless the patent is granted.

IV. when the request is made under above article 2, §1, line d, a copy of the expert report, issued by the Federal, State, City or Federal District Public Medical Service including proof of applicant’s medical condition;

V. when the request is made under above article 2, §1I:
   - a copy of the extrajudicial notification of patent application prioritized examination request, issued by the
relevant applicant or duly qualified attorney containing direct reference to the patent application number, applicant name and alleged undue action, or proof that the relevant applicant is charging the applicant of the prioritized examination of patent application with reproducing the subject-matter of the patent application; and the filing of pre-grant opposition to the technical examination, in order to prove that patent application subject-matter is in the state-of-the-art.

**Article 6.** When only one among several applicants carries out the procedures provided in this Rule, the applicant must issue relevant instrument putting others on notice.

**Article 7.** The person carrying out the procedures herein must hold power of attorney when he/she is not the relevant person, under article 216, ¶1 of Statute #9,279 of May 14, 1996.

**Article 8.** A committee of BRPTO officers will review patent application prioritized examination requests and the Patent Director will take the relevant decision.  
**Sole ¶.** This decision shall be published in the Electronic BRPTO Official Gazette.

**Article 9.** The BRPTO Rule #68, of March 18, 2013 is now revoked.

**Article 10.** This Rule enters into force on the date it is published in the Electronic BRPTO Official Gazette.

**LUIZ OTÁVIO PIMENTEL**  
President
Brazilian PTO Rule #80/2013 on fast-track patent examination of pharma related applications

This Rule establishes the rules for the priority examination of patent applications regarding pharmaceutical products and processes, as well as devices and materials related to public health. Published in the BRPTO Official Gazette #2205 of March 19, 2013.
THE VICE-PRESIDENT and the PATENT DIRECTOR of BRPTO, in the exercise of their assignments,

CONSIDERING Patent Statute #9,279 of May 14, 1996, establishing that the protection of the rights related to industrial property must reflect social interest and the technological and economic development of the country;

CONSIDERING the alignment of the BRPTO to the Greater Brazil Plan (Plano Maior Brasil), and to the public policy of health assistance provided by the Ministry of Health and to the development of the Industrial Health Complex;

CONSIDERING the needing to optimize the proceedings of examination of patent applications related to products, process, devices and materials regarding health sector, in particular those considered strategic to the National Healthcare System (SUS);

CONSIDERING the purpose of the BRPTO’s Priority Program – Solution to the Patent Backlog in reducing the delay in the examination of patent applications at levels consistent with best international practices;

CONSIDERING the needing to optimize the proceedings of operation processing of patent applications in order to obtain an improvement of efficiency quality;

DETERMINE:

**Article 1.** This Rule establishes the priority examination of patent applications regarding pharmaceutical products and processes, as well as devices and materials related to public health.

¶1. The priority examination of the patent applications related to article 1 can be requested by the Ministry of Health, as detailed in Section I of this Regulation;

¶2. The priority examination of patent applications related to article 1 can be requested by any interested when they refer to diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), cancer or neglected diseases, as detailed in Section II of this Regulation.

**Article 2.** The patent applications submitted to the priority examination, as established in this Regulation, will be under the responsibility of the Board of Patents - DIRPA.

**Sole ¶.** The Priority Examination Committee, selected by the Board of Patents – DIRPA -, will analyze the request for priority examination of patent applications.

**§1. Priorization of the Examination of Patent Applications as Per the Request of the Ministry of Health**

**Article 3.** The patent applications will be examined with priority when filed before the BRPTO, related products, processes, devices and/or materials used in health related to the National Policy of Pharmaceutical Assistance of the Ministry of Health and established as strategic to National Healthcare System.

§1. The patent applications are not limited to diagnosis, prophylaxis and treatment of the diseases listed in Annex 1 of this Rule;

§ 2. Patent applications must have been requested for technical examination, as provided in Article 33 of the Patent Statute.
Article 4. The list of patent applications submitted to priority examination request by the Ministry of Health will be established by the Committee of Priority Examination.

§1. The Board of Patents – DIRPA – will determine the grant or not of the prioritization of examination of patent applications;

§2. The list mentioned in article 4 can be established from the number of patent applications or from names or references to products, devices and/or materials for use in health related to the request of the Ministry of Health;

§3. In the case of names or references to products, devices and/or materials for use in healthcare, the BRPTO will identify their related patent applications.

§II. PRIORITY OF EXAMINATION OF PATENT APPLICATIONS AS PER THE REQUEST OF THE APPLICANT OR THIRD PARTIES

Article 5. The patent applications will be examined with priority when filed before the BRPTO, related products, processes, devices and/or materials used in health, directly related to the diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), cancer or neglected diseases.

Sole ¶. Neglected diseases are listed by the Ministry of Health and the World Health Organization (WHO), as per the Annex 1 of this Rule.

Article 6. The prioritization of examination of patent applications by the request of the applicant or third parties will be analyzed by the Priority Examination Committee.

Sole ¶. The Board of Patents – DIRPA – will determine if the patent application examination will be granted priority;

Article 7. For the granting of a priority examination of a patent application, the patent application shall be published in the BRPTO’s Gazette, as provided by Article 30 of the Patent Statute.

Sole ¶. The publication of the patent application can be anticipated as per the request of the applicant, as provided by ¶1 of Article 30 of the Patent Statute.

Article 8. For the granting of a priority examination of a patent application, it is necessary to have a request for technical examination, as provided by Article 33 of the Patent Statute.

Article 9. The request for priority examination for patent applications mentioned in Article 5 may be submitted by any interested party and by an application form. The application form (FQ009 - APPLICATION FOR PRIORITY EXAMINATION) is in PR Rule #63/2013.

Article 10. The acts of this Rule, when not practiced by the interested part, must be accompanied by POA, as provided by ¶1 of article 216 of the Patent Statute.

§IV. PRIORITY OF EXAMINATION – WORKFLOW

Article 11. The Commission of Priority Examination shall verify the patent applications meeting the following mandatory conditions for the granting of priority examination:

I. does not refer to the patent application whose examination is suspended for compliance with formal requirements previously formulated by the Board of Patents - DIRPA;
II. does not refer to a patent application of which has already been granted priority examination;
III. refers to the patent application that complies with the payment obligations of the annuities mentioned in Article 84 of the Patent Statute.

Article 12. The Board of Patents shall notify, in particular publication at the BRPTO’s Gazette, whenever the priority examination of the patent application has been granted.

Article 13. The Board of Patents shall notify, in particular publication at the BRPTO’s Gazette, whenever the priority examination of the patent application has been rejected.

§ V. General rules

Article 14. Article 4 of Rule #68 of March 18, 2013 is revoked.

Article 15. The priority examination mentioned in this Rule occurs without any charge for the interested.

Article 16. This Rule will enter into force on the date of its publication at the Official BRPTO Gazette.

JÚLIO CÉSAR CASTELO BRANCO REIS MOREIRA
Patent Director

ADEMIR TARDELLI
Vice-President
INTRODUCTION

Patent Prosecution Highway (PPH) is an international cooperation program between patent offices. The aim of the PPH is to support applicants in their efforts to obtain patent rights worldwide, to reduce the search/examination burden for patent examiners, and to improve the quality of examination by the major patent offices in the world. Therefore, the program provides for the sharing of search/examination between patent offices, to prioritize the patent application examination where the subject matter is considered patentable by another patent office, to foster international filing of the applications from Brazil, and to drive users into a more effective participation in work sharing mechanisms between offices.

The Patent Division and the USPTO created a 2-year pilot program with 150 openings in each office to implement this mode of cooperative priority examination. The program will be assessed and adaptations will be made over this period. A patent application will not be accepted unless a patent family member has been approved in the USPTO. An applicant must request prioritized examination, which is free during the pilot stage.

PPH ROUTES

At least one of the patent applications considered to belong to the SAME PATENT FAMILY must have been previously APPROVED in the USPTO so it can request prioritized examination with the BRPTO using PPH. Under the PPH, a patent family exists when the patent applications or granted patents share the same oldest prior art. In case of doubts concerning the definition of patent family, please see Chart 1 below.

A patent family is a set of patent applications filed or patents granted in more than one country so that the same invention designed by the same inventors is protected. A first patent application is filed in a country (the prior art) and is then expanded to other offices.

A Patent Family has 2 types of patent applications. Patent applications without prior art claim are called "First Patent Application" or "Source Document" or, in some cases, "Priority Document". Documents other than these are not accepted as prior art for the patent application filing in another national patent office or international organization, i.e. these are the only documents that can originate a patent family. The patent applications that otherwise claim the First Patent Application as prior art when filed are called "Second Patent Applications". When a Second Patent Application is filed, the First Application is then called "Prior Art Document". Below is a general explanation on patent families, discussing Table 1.

Consider that the Priority Document P1 is older than (was filed before) P2; and that the Prior Art Document P2 is older than P3. In this case, Family 1 is composed of 4 documents: the First Patent Application (or Priority) P1 and the Second Patent Application of Patents B, C and D as they share at least the oldest priority P1. Family 2 is composed of 3 members: Priority P2 and the Second Patent Applications E and F as they share at least the oldest priority P2. Family 3 is composed of 2 members: Priority P3 and the Second Patent Application G as they share at least the oldest priority P3.

Although Applications D and E share the same Priority P2, they do not belong to the same family, as they do not share the oldest priority (which is P1, in this case). This is also true for Patent Applications F and G, which do not belong to the same patent family, as they do not share the oldest priority P2.

Please note that the Documents of Priority P2 and Priority P3 do not belong to family F1. This is also true for Document of Priority P3, which does not belong to Patent Family F2.

Document A has no family, as it is a First Patent Application and has no priority, i.e. document A is the only Patent Application that is not able to participate in the PPH.

1 Source: http://www.jpo.go.jp/ppph-portal/aboutpph.htm
Table 2 shows three valid route types to participate in the PPH Pilot Program between the BRPTO and the USPTO: the “Type A Paris Routes (Paris Convention)”, the “Type C Paris Routes”, and the “Direct PCT Route”. In case of doubts on the stages of each route, please see the below charts.

<table>
<thead>
<tr>
<th>TABLE 2: valid routes to request priority examination via the PPH Pilot Program between the BRPTO and the USPTO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
</tr>
<tr>
<td><strong>Principle</strong></td>
</tr>
<tr>
<td><strong>Concept</strong></td>
</tr>
</tbody>
</table>

**Result of Examination of National Offices**

<table>
<thead>
<tr>
<th><strong>Paris Route (Paris Convention)</strong></th>
<th><strong>Direct</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1:OFF</td>
<td>1:OFF</td>
</tr>
<tr>
<td>Grant</td>
<td>Grant</td>
</tr>
<tr>
<td>2:OSF</td>
<td>2:OSF</td>
</tr>
<tr>
<td>Request for PPH</td>
<td>Request for PPH</td>
</tr>
<tr>
<td><strong>Already Implemented</strong></td>
<td><strong>Already Implemented</strong></td>
</tr>
</tbody>
</table>

**Subtitles**

**OFF:** Office of First Filing — OFF: The Patent Office where the first patent application is filed, without claim of priority.
**OSF:** Office of Second Filing — OSF: The Patent Office where the second patent application is filed, which claims priority.
**RO:** Receiving Office: Under the PCT, office able to receive international filings on behalf of the World Intellectual Property Organization.
**DO:** Designated Office: Office belonging to the country where applicant wishes to protect his/her invention and where filing to be examined enters national stage.

It is important to consider that the first filing must be made in the BRPTO or USPTO i.e. the OFF must be the BRPTO or USPTO. Should there not be a priority request, the BRPTO or USPTO is the RO. The application filed in the RO can have two or more priorities. In this case, the oldest priority must be BR or US. To request PPH in the BRPTO, OEE must be the USPTO. To request PPH in the USPTO, OEE must be the BRPTO. Any office can act as International Search Authority (ISA) or International Preliminary Examination Authority (IPEA). “Type B Paris Routes” and the “PCT-PPH Route” do not participate in the program.
1. Applicant files the First Patent Application (patent application without priority). Office where this application is made is called “Office of First Filing” — OFF;

2. Applicant files the Second Patent Application in another patent office and claims the First Patent Application as priority. Please note that both applications belong to the same patent family. The second patent office is called “Office of Second Filling” — OSF;

3. The Office of First Filing issues the first patent granting determination and becomes the “Office of Early Examination” — OEE. In our example, OFF was the first to examine, i.e. in this case, OFF is OEE as well. Therefore, this is the case of a “Type A” route. The remaining cases are described in the other Charts.

4. By definition, all of the other offices where the patent application of the same family was filed become an “Office of Late Examination” — OLE.

5. **This is when PPH can be requested.** Applicant may request participation in the PPH program in respect of the application of the same family that has already been examined in the OLE. In this case, OSF is OLE. Therefore, applicable OLE laws must me complied with, and the applicant must:
   a. Submit the results of search/examination to OEE;
   b. Change the claim chart so it matches the one accepted in the OEE;
   c. Attach a table showing the relationship between claims granted in the OEE and the changed claims;
   d. Submit remaining required documents.

6. If the documents submitted are correct, a patent application is able to participate in the PPH program and its examination is going to be prioritized;

7. Finally, OLE examines the patent application of the same family as the patent application approved by the OEE by using regular search/examination procedures and complying with local laws.

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**Figure 1:** Example of “Type A Paris Route” PPH stages

- **Without priority**
  - **Patent application with subject matter A**
    - 1. Reasons for rejection
    - 2. Filing of Patent Application of Same Family A
    - 3. Acceptance Determination

- **Claims priority**
  - **Filing of Patent Application of Same Family A**
    - 2. Submission of examination results; Changing claim chart; Submission of correlation table; Other required documents;
    - 3. Request of Participation in PPH
    - 4. Prioritized Examination
    - 5. Regular search/examination procedure
1. Applicant files First Patent Application (patent application without priority). Office where this application is made is called “Office of First Filing” — OFF;

2. Applicant files the Second Patent Application in another patent office and claims the First Patent Application as priority. Please note that both applications belong to the same patent family. The second patent office is called “Office of Second Filing” — OSF;

3. The National Offices of Second Filing issues the first patent grant determination and becomes the “Office of Early Examination” — OEE. In our example, OSF was the first to examine, i.e. in this case, OSF is OEE as well. Therefore, this is the case of a “Type C” route.

4. By definition, all of the other offices where the patent application of the same family was filed become an “Office of Late Examination” — OLE.

5. This is when PPH can be requested. Applicant may request participation in the PPH program in respect of the application of the same family that has already been examined with the OLE. In this case, OFF is OLE. Therefore, applicable OLE laws must be complied with and the applicant must:

   a. Submit the results of search/examination to OEE;
   b. Change the claim chart so it matches the one accepted in the OEE;
   c. Attach a table showing the relationship between claims granted in the OEE and the changed claims;
   d. Submit remaining required documents.

6. If the documents submitted are correct, the patent application is able to participate in the PPH program and its examination is going to be prioritized;

7. Finally, OLE examines the patent application of the same family as the patent application approved by the OEE by using regular search/examination procedures and complying with local legislation.

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**Figure 2: Example of “Type C Paris Route” PPH stages**

**Chart 3: Example of “Type C Paris Route” PPH stages**

1. Applicant files First Patent Application (patent application without priority). Office where this application is made is called “Office of First Filing” — OFF;

2. Applicant files the Second Patent Application in another patent office and claims the First Patent Application as priority. Please note that both applications belong to the same patent family. The second patent office is called “Office of Second Filing” — OSF;

3. The National Offices of Second Filing issues the first patent grant determination and becomes the “Office of Early Examination” — OEE. In our example, OSF was the first to examine, i.e. in this case, OSF is OEE as well. Therefore, this is the case of a “Type C” route.

4. By definition, all of the other offices where the patent application of the same family was filed become an “Office of Late Examination” — OLE.

5. This is when PPH can be requested. Applicant may request participation in the PPH program in respect of the application of the same family that has already been examined with the OLE. In this case, OFF is OLE. Therefore, applicable OLE laws must be complied with and the applicant must:

   a. Submit the results of search/examination to OEE;
   b. Change the claim chart so it matches the one accepted in the OEE;
   c. Attach a table showing the relationship between claims granted in the OEE and the changed claims;
   d. Submit remaining required documents.

6. If the documents submitted are correct, the patent application is able to participate in the PPH program and its examination is going to be prioritized;

7. Finally, OLE examines the patent application of the same family as the patent application approved by the OEE by using regular search/examination procedures and complying with local legislation.
1. Applicant files the First Patent Application (patent application without priority) directly with the Receiving Office – RO. In this case, RO is the WIPO. Please note that there is not an OFF. This Route is named after the direct deposit in the RO.

2. The application enters national stage in the Designated Offices – DO. Please note that all applications belong to the same patent family. Please note that there is not an OSF.

3. One of the national offices issues the first patent granting determination and becomes the “Office of Early Examination” — OEE.

4. By definition, all of the other offices where the patent application of the same family was filed become an “Office of Late Examination” — OLE.

5. This is when PPH can be requested. Applicant may request participation in the PPH program in respect of the application of the same family that has already been examined with the OLE. Therefore, applicable OLE laws must be complied with and the applicant must:
   a. Submit the results of search/examination to OEE;
   b. Change the claim chart so it matches the one accepted in the OEE;
   c. Attach a table showing the relationship between claims granted in the OEE and the changed claims;
   d. Submit remaining required documents.

6. If the documents submitted are correct, the patent application is able to participate in the PPH program and its examination is going to be prioritized;

7. Finally, OLE examines the patent application of the same family as the patent application approved by the OEE by using regular search/examination procedures and complying with local legislation.
Chart 5: Other examples of creation of patent families able to participate in the PPH Pilot Program between the BRPTO and the USPTO

- **Patent Family with internal priority claim.**
  - Patent Application in the USPTO
  - Internal Priority
  - Patent Application in the USPTO
  - Claims US Priority
  - Patent Application in the BRPTO

- **Patent Family with more than one priority claim where either US or BR is the oldest claim.**
  - Patent Application in the USPTO (oldest)
  - Patent Application from office other than the USPTO
  - Claims US Priority
  - Claims priority

- **Patent Family claiming priority of a national filing in the USPTO or BRPTO in respect of the international filing in any RO.**
  - Patent Application in the USPTO
  - Claims US Priority
  - PCT Request USPTO as ISA or IPEA
  - BRPTO as ISA or IPEA
  - National stage of patent application in the USPTO
  - National stage of patent application in the BRPTO

- **Patent Family with priority claim of an international filing in the BRPTO or USPTO, national filing in the BRPTO or USPTO.**
  - PCT Request USPTO as ISA or IPEA
  - BRPTO as ISA or IPEA
  - National stage of patent application in the USPTO
  - National stage of patent application in the BRPTO
  - Claims priority
  - Patent Application in the BRPTO

- **Patent Family claiming priority of a national filing in the USPTO or BRPTO in respect of the national filing in any RO.**
  - PCT Request USPTO as ISA or IPEA
  - BRPTO as ISA or IPEA
  - National stage of patent application in the USPTO
  - National stage of patent application in the BRPTO
  - Claims priority
  - Patent Application in the BRPTO
ELIGIBILITY REQUIREMENTS

The patent application must comply with the following requirements to participate in the BRPTO-USPTO PPH Pilot Program:

1. The application must entail a patent of invention or utility model;
2. The patent application must be filed with the BRPTO after 2 November 2012;
3. The patent application where claimed subject matter belongs to the oil & gas industry, classified as one of the symbols in the International Patent Classification — IPC, including IPC’s relevant lower levels of classification.
4. The patent application belonging to a patent family; for PPH purposes, a patent family is a set of filed patent applications and granted patents where all patents claim, at least, the oldest priority document. Such applications and patents can be filed or granted in more than one national patent office or international organization.
5. The patent application claiming at least the oldest valid priority, under the Paris Convention, originated in Brazil or in the USA;
6. The patent application whose family member was accepted by the USPTO;
7. The application must be published in the BRPTO Official Gazette. If the application was not published, applicant or legal attorney must issue and pay the corresponding fee of a Federal Tax Liability Payment Form (GRU) for “Advanced Publication” services, coded 202. The Federal Tax Liability Payment Form can be found at http://formulario.inpi.gov.br/e-inpi/internetCliente/Principal.jsp.
8. The application must contain the examination request. If the application does not contain the examination request, applicant or legal attorney must issue and pay the corresponding fee of a Federal Tax Liability Payment Form (GRU) for “Invention Examination Request (no petition required)” services, coded 203.
9. The patent application progress cannot be suspended for compliance with requested claim(s);
10. The application must be up to date with annuity payment. If annuity payment is in default, applicant or his/her legal attorney must issue and pay the corresponding fee of a GRU in respect of invention patent annuity payment, through codes 220-229, according to each application. Codes 240-247 must be used when application entails a utility model.
11. No other prioritized examination has been accepted for patent application;
12. The subject matter cannot be subject to judicial challenge in Brazil; and
13. The patent application that is not the original application of a divisional application or application arising from divisional of another patent application, except for direct divisional of original application when OEE claims the application lacks unity of invention or technical/functional unity;
14. The patent application technical examination must not have been published in the BRPTO Official Gazette;

REQUIRED DOCUMENTS AND STATEMENTS

Proof that a family member of the application in question has been granted a patent is required for program participation. The below documents are required:

1. Document proving that the application first filed with the BRPTO has a patent family, such as filing certificates issued by patent offices or international organizations or patent application publications.
2. Proof that the application entails oil & gas industry. The document may contain the specification excerpt related to the subject matter or classification made by patent offices.
3. Translation into Portuguese of the search and examination made by the USPTO.
4. Translation into Portuguese of the claim charts considered patentable by OEE and the claim charts changed and submitted to the BRPTO.
5. A Correlation Table of the claims considered patentable by the OEE and the claim charts changed and submitted to the BRPTO. The Correlation Table lists claims accepted in the BRPTO with the new claim chart submitted to the BRPTO. See the model below, in Table 3. If the claim chart that has been changed and submitted to the BRPTO matches the simple translation of the claim chart accepted by the USPTO, a simple statement will do. Please be reminded that the scope of the claim chart must be matching or stricter and that the changes must comply with the examination guidelines.

<table>
<thead>
<tr>
<th>Claim accepted by the BRPTO</th>
<th>Changes in the Claim Chart submitted to the BRPTO</th>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Claim 1 submitted to the BRPTO matches the simple translation of claim 1 considered patentable by the USPTO.</td>
</tr>
<tr>
<td>2</td>
<td>2 and 3</td>
<td>Claim 2 accepted by the BRPTO was split into claims 2 and 3 submitted to the BRPTO so it complies with applicable laws.</td>
</tr>
<tr>
<td>3 and 4</td>
<td>4</td>
<td>Claims 3 and 4 granted by the USPTO were grouped into claim 4, submitted to the BRPTO so it complies with applicable laws</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>Claims 5 accepted by the USPTO match claim 5 submitted to the BRPTO, only restricted with the excerpt added...</td>
</tr>
</tbody>
</table>

6. Translation into Portuguese or Spanish of state-of-the-art references cited in the OEE examinations that are not already in such languages;

7. **Additional documents must be attached in special cases**;

8. If applicant has a legal representative, copy of power of attorney must be attached;

9. Documents that are not listed in the “Attached Documents” section must be submitted via specific form accompanying payment of the relevant GRU.

10. Statements required to participate in the PPH Pilot Program between the BRPTO and the USPTO are listed in the Patent Prosecution Highway Program Participation Request Form. **Therefore, statements do not have to be submitted in a separate document.**

**Next section**

Unless there is a patent or utility model application being prosecuted in the BRPTO, participation in the PPH program cannot be requested. For additional information on patent application filing, see the Manual for Patent Applicants, which can be found at [http://www.inpi.gov.br/menu-servicos/patente/guia-basico-de-patente](http://www.inpi.gov.br/menu-servicos/patente/guia-basico-de-patente) (in Portuguese).

The applicant or his/her legal representative must use the Prioritized Examination Request form so the request is progressed. The form can be completed in a paper-based copy or electronic. Electronic petitioning is the preferred method, not only because the BRPTO processing time is reduced, but also because it is more practical for the user. If paper-based copy is utilized, the Prioritized Examination Request Form must be sent to the BRPTO with delivery receipt, along with copies of the documents listed in the item “Attached Documents”. If electronic petitioning is utilized, the form must be submitted to the BRPTO along with a digital copy of the documents listed in the item “Attached Documents”.
**PARTICIPATION REQUEST**

The participation must be requested by the patent application owner before termination of the program. First, the applicant or his/her attorney must issue the GRU for “Prioritized Examination” services so that PPH prioritized examination is requested. The GRU can be issued at [http://formulario.inpi.gov.br/e-inpi/internetCliente/Principal.jsp](http://formulario.inpi.gov.br/e-inpi/internetCliente/Principal.jsp), under code 263. GRU 263 is free of charge.

In the “Interested” section of the Prioritized Examination Request form, the applicant must complete his/her personal details. It is worth noting that only the applicant can request prioritized examination for this pilot program, i.e. third parties are forbidden to take part in this service.

In the “Reference” section of the Prioritized Examination Request form, the applicant must enter data of the invention or utility model patent application for which prioritized examination is sought. The chart referring to the nature of the application must be highlighted (if entailing an invention or utility model patent). In addition, the patent application number and date must be completed.

The “Attorney” section of the Prioritized Examination Request form must be completed if the applicant has a legal representative. In addition, a designated attorney must check the “Power of Attorney” box in the “Attached Documents” section, and attach a simple copy of the power of attorney to the form. This field should be left blank where there is no legal representative.

In the “Attached Documents” section of the Prioritized Examination Request form, the applicant must check all boxes pertaining to the items he/she deems necessary. In addition, applicant must attach relevant documents to the Prioritized Examination Request form.

When a patent application has more than one applicant, all applicants must acknowledge the Prioritized Examination Request. In this case, the box “Acknowledgment of Other Applicants”, in the section “Attached Documents” must be checked and relevant acknowledgment statements must be attached to the prioritized examination request.

Documents not listed in the “Attached Documents” section must be attached via specific form accompanying payment of the relevant GRU, if needed. Specifically, if the application entails national genetic heritage and the associated traditional knowledge, form FQ011 must be submitted for Communication of the Access Authorization Number (CGEN authorization) (service code 264); or form FQ012 for Statement of Non-Access to The National Generic or Cultural Heritage (CGEN) (service code 273); both service codes 264 and 273 are free of charge.

**FLOW OF PROCEEDINGS**

The date of request to enter the Prioridade BR Pilot Program corresponds to the date of receipt of the prioritized examination request petition at the BRPTO headquarters or relevant Regional Divisional Offices and/or representation offices in each state or the date of receipt of electronic form.

The BRPTO shall publish the Prioritized Examination Request of patent application in the BRPTO Official Gazette, using objection code 15.24. The Prioritized Examination Request assessment shall follow the chronological order of service request date.
The BRPTO shall publish the acceptance of a prioritized examination of patent application in the BRPTO Official Gazette using objection code 15.24.2. Once accepted, the prioritized examination shall not be initiated until 60 calendar days after publication of request which is provided for in article 30 of the Brazilian IP Statute. After this term, the patent application shall be forwarded to the patent divisional for the patent divisional to make the relevant examination. The applicant must check the BRPTO Official Gazette for execution of technical examination of his/her patent application. It is the user’s exclusive responsibility to do so.

The BRPTO shall publish the rejection of prioritized examination of the patent application in the BRPTO Official Gazette, using objection code 15.24.3. The applicant may submit the new Prioritized Examination Request before termination of the pilot program, when the application is not considered able provided he/she has resolved any objections made by the BRPTO. The applicant is exempt from re-submitting any documents in respect of which no objections were made. New prioritized examination requests under the pilot program regulated by the BRPTO Rule #153/2015 shall not be accepted when the pilot program deadline has expired and when the maximum number of application openings for the program has been reached.

All information for the applicant in respect of objection codes 15.24, 15.24.2 and 15.24.3 as well as technical opinions arising from any prioritized examination acceptance shall be made publicly available on the BRPTO’s e-Parecer system (http://eparecer.inpi.gov.br/eparecer.php).

**Additional Information**

Additional details on the PPH Pilot Program are available in the Rule dealing with this topic (BRPTO Resolution #153/2015). For more information, please access the BRPTO Portal at (http://www.inpi.gov.br/menu-servicos/patente/acelere-seu-exame) or the PPH portal at (http://www.jpo.go.jp/ppph-portal/index.htm?utm_source=twitterfeed&utm_medium=twitter). You can also e-mail us at PPH@inpi.gov.br.
Rule #154/2015

This rule concerns the administrative proceedings of the Pilot Project of Shared Prioritized Examination Patent Prosecution Highway — PPH.
By exercising the powers vested in them by the BRPTO Bylaws, and considering the provisions of Statute #9 279, of May 14, 1996 (Brazilian IP Statute), as well as articles 159, §IV and article 106 of the BRPTO Bylaws, which is attached to Order #149 of the Ministry of Development, Industry and Foreign Commerce of May 13, 2013, and


CONSIDERING the Memorandum of Understanding between the BRPTO and the United States Patent and Trademark Office — USPTO, of November 19, 2015, and the relevant Work Plan established between the Offices; and

CONSIDERING the principles of territoriality and independence of intellectual property rights,

THE PRESIDENT OF THE BRAZILIAN PATENT AND TRADEMARK OFFICE (BRPTO) and the PATENT DIRECTOR DETERMINE:

Article 1. This Rule concerns the administrative proceeding of the Pilot Project of Shared Examination Patent Prosecution Highway — PPH established between the BRPTO and the USPTO, hereinafter BRPTO-USPTO PPH Pilot Project, under the BRPTO.

Article 2. For the purposes of this Rule, definitions are as follows:

I. First Patent Application: a patent application filed in the BRPTO or the USPTO without priority claim that can be used as priority document for a second patent application filing in another national Patent Office or international organization and that can create a patent family; or international filing, under the PCT, without priority claim, where the BRPTO or the USPTO is appointed as receiving office, in which case the patent application can enter national phase and create a patent family;

II. Second Patent Application: A patent application filed in the BRPTO or the USPTO and that is part of the patent family of the first patent application; or a patent application that entered national phase in the BRPTO or USPTO composing the patent family of the first patent application;

III. Patent Family: a collection of patent applications filed in more than one national Patent Office or international organization, where all of them claim at least the oldest priority;

IV. Office of First Filling — OFF: The Patent Office where the first patent application is filed;

V. Office of Second Filling — OSF: The Patent Office where the second patent application is filed;

VI. Office of Earlier Examination — OEE: The national Patent Office (the BRPTO or the USPTO) that first issues a decision of patent grant of an application belonging to the patent family, be it the OFF or OSF;

VII. Office of Later Examination — OLE: The national Patent Office (the BRPTO or the USPTO) where PPH is requested and that prioritizes prosecution and examines a patent application belonging to the same patent family based on OEE results;

VIII. Able Patent Application: A patent application complying with eligibility conditions set out in Article 7 of this Rule; and

IX. Date of request: date of receipt of PPH request of shared prioritized examination at the BRPTO headquarters, or relevant regional divisional offices and/or representation offices in each State, or via electronic form, or date of posting should the request be sent via mail.

X. Sufficiently corresponding application: an application where the matter described in the application filed in the OLE does not amend or change the subject matter deemed patentable in the corresponding OEE application, even when translation inconsistencies are considered, and when both of them belong to the same patent family;
XI. Sufficiently corresponding claim: a claim where a claimed matter in the OLE is of the same or narrower scope of the subject matter deemed patentable in the corresponding OEE application, even when translation differences are considered; and
XII. Narrower claim scope: a claim scope is narrower when it is limited, under Article 32 of the Brazilian IP Statute and the BRPTO Rule #93, of June 10, 2013.

Article 3. For the purposes of this Rule, the following steps should be followed for PPH to apply:
I. Applicant files first patent application, which turns the receiving national Office or international organization into the OFF;
II. Applicant files second patent application by claiming priority of the first patent application as priority or entering national phase, which turns the receiving national Office into the OSF;
III. National Office that issues the first patent grant, either from first or second patent application, becomes the OEE;
IV. Applicant requests participation in BRPTO-USPTO PPH Pilot Project by meeting requirements and submitting results of the first patent grant to the other national Office, which becomes OLE; and
V. When the application is considered able, OLE prioritizes the patent application belonging to the same family in every following step, until the final decision.

Sole ¶. Any waiver of the First Patent Application that was used as priority for international filing under the PCT does not exempt the participation of the corresponding entries into national phase in the BRPTO-USPTO PPH Pilot Project.

Article 4. The applicant of a patent application accepted in the USPTO may request a prioritized examination of an application of the same family in the BRPTO, should the application meet the requirements of this Rule.

Article 5. The BRPTO-USPTO PPH Pilot Project should accept participation requests for a period of two years, or the Pilot Project should extend until every application considered able has a final decision.

Article 6. The BRPTO will examine no more than 150 applications as OLE.
¶1. The examination mentioned in the main section of this article is completed chronologically as per date of request to participate the BRPTO-USPTO PPH Pilot Project.
¶2. The applications able to participate in the BRPTO-USPTO PPH Pilot Project that exceed the limit set out in the main section of this article will not be included in the Project.

Article 7. For the purposes of the BRPTO-USPTO PPH Pilot Project, the following requirements for prioritized examination are made:
I. Patent application filed in the BRPTO from January 1, 2013 onwards;
II. Utility patent application;
III. Patent application published at the BRPTO Official Gazette — RPI (in the Portuguese abbreviation) under the provisions of article 30 of the Brazilian IP Statute, or patent application published in advance upon applicant’s request under ¶1 of article 30 of the Brazilian IP Statute, or patent application that has been accepted in the admissibility examination to enter national phase filed via PCT;
IV. Patent application for which a request for examination has been requested, under the provisions of article 33 of the Brazilian IP Statute;
V. Patent application where examination is not pending answer to office action previously made by the BRPTO;
VI. Patent application that has not defaulted payment of annuity under article 84 of the Brazilian IP Statute;
VII. Patent application where request for prioritized examination was not granted and published in the BRPTO Official Gazette;
VIII. Patent application that is not being judicially challenged in Brazil;
IX. Non-divisional patent applications, except those arising from direct division of the original application, as a result of a lack of unity of invention objection from the OEE, in the sufficiently corresponding application;
X. Patent application that has not undergone regular technical examination duly published in the BRPTO Official Gazette;
XI. Patent application where claimed subject matter explicitly belongs to the oil, gas, or petrochemical industry, and classified as any of the symbols in the International Patent Classification — IPC, including IPC’s relevant hierarchal lower levels of classification, found in Annex I of this Rule;
XII. Patent application belonging to a patent family, under Article 2 of this Rule;
XIII. Patent application where family member received a notice of allowance from the USPTO;
XIV. Patent application where family has at least the first patent application filed in the BRPTO or USPTO;

¶1. Utility model and design applications are excluded from the BRPTO-USPTO PPH Pilot Project.
¶2. “Plant patent applications”, “reexamination applications”, “reissue applications” and “industrial design applications” should not be used as basis to request participation in the BRPTO-USPTO PPH Pilot Project.

Article 8. Admission request in the BRPTO-USPTO PPH Pilot Project provided for in this Rule should be made via Service Code #277 of the Table of Fees of Patent Services Provided by the BRPTO. However, applicant is not exempt from remaining fees pertaining to patent application prosecution.

Article 9. When the BRPTO acts as OEE of a patent application with family member in the USPTO, applicant may request participation in the BRPTO-USPTO PPH Pilot Project in the USPTO, by complying with the provisions set out by the USPTO.

Article 10. For admission in the BRPTO-USPTO PPH Pilot Project, only the applicant may request for participation by using the Patent Prosecution Highway Project Participation Request Form.
Sole ¶. When a patent application has more than one applicant, all applicants should acknowledge the participation request.

Article 11. When an individual other than applicant practices the acts provided for in this Rule, a power of attorney should be submitted in addition, under ¶1 of Article 216 of the Brazilian IP Statute.

Article 12. Applicant should submit the following documents and information in Portuguese to the BRPTO upon requesting admission in the BRPTO-USPTO PPH Pilot Project of a patent application:
I. Prioritized Examination Request Form;
II. New pages of patent application adapted to sufficiently match the allowed subject matter that the OEE previously set out as accepted; pages should comply with applicable rules on patent application submission to the BRPTO;
III. A Claim Correspondence Table of the claim charts comparing new claims submitted to the BRPTO and the claims considered to be allowable/patentable by the USPTO as OEE, under model in Annex II of this Rule;
IV. Proof that the application falls within technology industry which is able to participate in the Pilot Project, pursuant to line XI, Article 7 of this Rule;
V. When the object of a patent application is a result of access to component of Brazilian genetic heritage or associated traditional knowledge, the information required under applicable laws should be provided,
accompanied by request for the BRPTO-USPTO PPH Pilot Program,
VI. When the OEE technical examination report mentions non-patent prior art references, those documents
should be submitted along with request for the BRPTO-USPTO PPH Pilot Program:
Sole¶.
When claims submitted to the BRPTO are a mere translation of claims accepted by the USPTO as OEE, the
Claim Correspondence Table described in Section III of this article can be replaced with a corresponding declaration.

Article 13. Applicant should submit the following statements, in Portuguese, to the BRPTO when applicant
requests participation in the BRPTO-USPTO PPH Pilot Project or enters these in the Prioritized Examination
Request Form:
I. That all copies of OEE actions, when submitted to the BRPTO, correspond to the original documents and
replicate their form and content;
II. That translations, when submitted to the BRPTO, match the contents of the original documents;
III. That the patent application is not being judicially challenged in Brazil; and
IV. That the patent application does not arise from voluntary division of patent application.

Article 14. The Patent Board (DIRPA, in the Portuguese abbreviation) is responsible for checking requirements of
prioritized examinations and eligibility of patent applications that may participate in the BRPTO-USPTO PPH Pilot
Project through the Shared Prioritized Examination Project Work Group.

Article 15. When the submitted patent application is considered able to participate in the BRPTO-USPTO PPH Project,
the BRPTO should provide a specific notification of the acceptance of the prioritized examination of patent application
in the Brazilian Official Gazette publication.

Article 16. When the patent application is not considered able to participate in the Pilot Project or exceeds the limit
of openings, the BRPTO should notify the rejection of prioritized examination of patent application in the Brazilian
Official Gazette.
¶1. When a prioritized examination is rejected, the patent application resumes ordinary prosecution.
¶2. When the BRPTO points out remediable irregularities, applicant may submit a single additional priority
examination request within 60 days, pursuant to Article 224 of the Brazilian IP Statute by correcting any
the irregularities; applicant is exempted from re-submitting any documents for which no irregularities were
pointed out.

Article 17. Pursuant to article 212 of the Brazilian IP Statute, the decisions provided for in this Rule cannot be appealed.

Article 18. When prioritized prosecution is granted, patent application examination should not commence until 60
days after its publication, under article 31 of the Brazilian IP Statute.

Article 19. The BRPTO-USPTO PPH Pilot Project does not affect the fundamental principle of independence of
exams set out in Article 4bis of the Paris Convention for the Protection of Industrial Property.

Article 20. The BRPTO-USPTO PPH Pilot Project does not exempt the applicant from complying with the provisions
of the Brazilian IP Statute on patent applications filed in the BRPTO.

Article 21. Patent application examinations made via the BRPTO-USPTO PPH Pilot Project should comply with
Brazilian laws and other proceedings applicable on the date of examination.
Article 22. Throughout the prosecution of the application, the BRPTO may request that the applicant submits copies of the following documents in respect of the technical examination throughout the technical examination period:
   I. Copy of search reports, office actions made by OEE and applicant's answers to such reports;
   II. Copy of claims considered to be allowable/patentable by OEE;
   III. Copy of prior art documents mentioned by OEE in its technical examination reports;

Sole¶. Documents requested by the BRPTO that are originally not in Portuguese, Spanish or English should be submitted to the BRPTO with a simple translation into one of these languages, at the applicant's discretion.

Article 23. This Rule enters into force on January 11, 2016.

LUÍZ OTÁVIO PIMENTEL
President

JÚLIO CÉSAR CASTELO BRANCO REIS MOREIRA
Patent Director
Brazilian PTO Rule #93/2013
on claim amendments and divisional applications

This Rule establishes the guidelines regarding the applicability of article 32 of the Patent Statute #9,279 of 1996, on claim amendments and divisional applications. Published in the Industrial Property Gazette #2215 of June 18, 2013.
Part 1

1.1. Definitions

1. Brazilian IP Statute – Statute #9,279/96, of May 14th 1996.
2. Article 32 of the Brazilian IP Statute: To better clarify or define the patent application, the applicant may make changes until the examination request is filed, provided that these are limited to the subject matter initially disclosed in the application.
3. Disclosed Matter: Correspond to all matter contained in the patent application presented by the Applicant at the time of filing, which are: specification, claims, draws (if any), abstract or sequence listing (if any).
4. Claimed Matter: Correspond to the set of claims contained in the claim chart. The subject matter disclosed is wider, i.e., not everything that is contained in the specification is found in the claim chart presented by the Applicant.
5. Valid claim chart: Refers to the claim chart presented by the Applicant until the date of the examination request of the patent application (or the claim chart filed with this request, if any).
6. Original Application: Refers to the patent application that originated the first Divisional Application, independently of the occurrence of other divisional from this first Divisional Application.
7. Request for Examination: Refers to the petition through which the applicant of a patent application requests the technical examination of the said application. Represents the time limit established by Article 32 of the Brazilian IP Statute for the presentation [submission] of voluntary amendments to the claim chart based on the subject matter disclosed.
8. Second Instance: Refer to the decisions issued by the President of the BRPTO (Brazilian PTO), within the scope of the Appeals and Administrative Proceedings for Nullity. In this Rule, the acronym CH will refer to the Claim Chart.

1.2. Clarifications

- The Technical Opinion PROC/DICONS #07/2002 established that Article 32 of the Brazilian IP Statute WOULD NOT prevent that, after the examination is requested, changes are made into the Claim chart to add matter that already had been DISCLOSED in the originally filed application. The publication of this decision occurred in the BRPTO Official Gazette #1,655 of Sep 24, 2002.
- In 2003, the Federal District Attorney (Federal District Attorney (MPF)), driven by a group of examiners of the Brazilian PTO, filed civil public action #2003.51.01.513584-5 against the Brazilian PTO contesting the standardization and application of the technical Opinion PROC/DICONS #07/2002 within the Brazilian PTO.
- In 2007, the Brazilian PTO recognized the merits of the action filed by the Federal District Attorney (MPF) and proceeded to repeal the Technical Opinion PROC/DICONS #07/2002, as notified in BRPTO Official Gazette #1886 of Feb 27, 2007. The MEMO/Brazilian PTO/Board of Directors/No.030/2008, of Feb 27, 2008, established the first administrative procedures for guiding the technical divisions in the examination of patent applications that presented voluntary amendments to the claim chart, in light of the provisions contained in Articles 26 and 32 of the Brazilian IP Statute. The MEMO/Brazilian PTO/Board of Directors/#072/2008 of Apr 24, 2008, established procedures governing the applicability of the provisions of Article 32 of the Brazilian IP Statute in the technical examination performed by Brazilian PTO's first instance departments. The procedure would also apply to all applications that had not been decided yet and present request for changes to the claim chart that were accepted by the examiner during the period in which the Technical Opinion PROC/DICONS #07/2002 was in force.
• The Technical Opinion BRPTO/PROC/CJCONS #012/2008, of May 23, 2008, issued by the Brazilian PTO’s Chief Attorney, ratified the interpretation of the provisions of Article 32 of the Brazilian IP Statute and the repeal of the Technical Opinion PROC/DICONS No 007/02, in respect to its interpretation of the provision of Article 32 of the Brazilian IP Statute to patent applications, based also by the grounds of the judicial decision issued by the Federal Court of Appeals for the 2nd Circuit (TRF-2) published in the Brazilian Official Gazette dated Aug 24, 2007, contained in pages #392/421, which acquired nonappealable status on Oct 31, 2007.

• The Order #08/2010 issued by the Brazilian PTO’s Chief Attorney, established procedures for the application of Article 32 of the Brazilian IP Statute in patents applications resulting from the division of an Original Application. In this Order, the Chief Attorney concluded that patents applications that resulted from the division of an application, in accordance with article 26 of the Brazilian IP Statute, when this division occur after the date of examination request of the original patent application, will be subject to the time limit specified in Article 32 of the Brazilian IP Statute, that is, said application’s claim chart will not be allowed to be subject to voluntary amendments.

From the aforementioned, it is concluded that, according to the wording of Article 32 of the Brazilian IP Statute, the amendment of a patent application will only be allowed when required up to the date in which the request for examination is filed, and provided that the amendment requested is limited to the matter initially disclosed and aims to satisfy the need for a better clarification or definition thereof. This understanding is reiterated by the repeal of the Technical Opinion PROC/DICONS #07/2002 (published in the BRPTO Official Gazette #1886 of Feb 27, 2007), the civil action #2003.51.01.513584-5 and the grounds of the judgment issued by the Federal Court of Appeals for the 2nd Circuit (TRF-2) published in the Brazilian Official Gazette dated Aug 24, 2007, contained on its pages #392/421, which acquired nonappealable status on Oct 31, 2007. The documents MEMO/BRPTO/Board of Directors/#059/2008, the Technical Opinion BRPTO/PROC/CJCONS #012/2008 and the Order #08/2010 of Brazilian PTO’s Chief Attorney support this position.

In regard to the terms “originally disclosed” and “initially claimed,” the Brazilian PTO’s Attorney Office (see Order #08/2010 of the Chief Attorney) established that the term “disclosed” refers to the documentation submitted at the time of filing of the patent application (specification, claim chart, short, drawings (if any), sequence listing (if any) and/or supplemented by any corrections or restatements of such documents, until the request for examination of said patent application is filed.

According to the understanding stated in the Technical Opinion BRPTO/PROC/ CJCONS / #012/2008, Article 32 of the Brazilian IP Statute establishes the date in which the request for examination is filed as the end of the time limit for requesting voluntary amendments in the claim chart, provided that the change requested aims to clarify or better define the claimed matter and are limited to the subject matter initially disclosed.

The voluntary amendments that aim to correct or reduce the scope of protection initially claimed are not subject to the time limit specified in Article 32 of the Brazilian IP Statute. Considering the item II of the MEMO/PTO/Board of Directors/ #072/08 (#072/08 Apr 25, 2008), the same rationale also applies to changes made to the claim chart’s content resulting from the applicant’s reply to technical examination opinions.

It should be noted that, according to Order #08/2010 of the Brazilian PTO’s Chief Attorney (see page 2 – 3rd paragraph), in verbis: “Thus, we understand that a voluntary change of the claim chart of a divisional patent application may only occur if the said division has occurred prior to the date in which the request for examination of the Original Application is filed. With effect, this means that in the case that the division of a patent application
occurred after the request for examination is filed, the change to the claim chart is prohibited, in obedience to the intelligence of Article 32 of Statute #9,279/96.”

Thus, it is valid to use Article 32 of the Brazilian IP Statute as a finalist provision in regards to the technical examination, that is, a patent application, when required, should be rejected on grounds of Article 32 of the Brazilian IP Statute.

**PART 2**

**Harmonization of the Application of the Provisions of Article 32 of the Brazilian IP Statute in the Exam of Patent Applications**

**2.1. Changes to be allowed on the Claim Chart**

After the request for examination of a patent application is made no voluntary amendment to the claim chart will be accepted if they result in expanding the subject matter claimed.

(I) Until the date in which the request for examination of a patent application is filed will be accepted changes to the specifications, claim chart (even to expand the subject matter claimed), abstract, drawings (if any), sequence listing (if any), PROVIDED THAT LIMITED INITIALLY THE MATTERS DISCLOSED.

(II) Changes that aim to correct unequivocal typing error or translation will be accepted AT ANYTIME OF THE PROCESSING OF THE PATENT APPLICATION EXAMINATION, not being subject to the time limit established in Article 32 of the Brazilian IP Statute. These changes, however, must be supported by matter contained in: (1) the priority document (if any), (2) in the specification, (3) in the abstract, (4) in the drawings, if any; (5) in international filing, if any; (6) in the sequence listing, if any, (7) in the biological material filing, or (8) in the claim chart.

(III) Changes submitted by the Applicant for the purpose of adequating the claims to the provisions of Rule #PR #17/2013 (formerly Normative Act 127). Non-exhaustive examples include: (a) lack of the transitional phrase (characterizing expression), (b) error concerning the dependency relationships between the claims, (c) inclusion of numerical references to the drawings, may be accepted for reasons of procedural economy (pursuant the provisions of Article 220 of Brazilian IP Statute).

(IV) After the request of patent application examination is filed will be also accepted changes in the claim chart, voluntary or resulting from technical examination (office actions #6.1 or #7.1), provided that they serve solely to restrict the claimed subject matter and do not alter the object sought. Non-exhaustive examples of forms of restrictions to be supported include:

- insertion of information of a dependent claim to an independent claim;
- restriction of parameter ranges;
- removal of an element originally submitted in an alternatively way (initially it was envisaged that a product contains items A or B, and the new framework provides only the item A);
- adequating the nature of the patent application.

**2.2. Changes not allowed on Claim Set**

(I) After the request of the examination of the patent application is filed will not be accepted modifications that result in expansion of the CLAIMED subject matter.

(II) Changes in the CLAIM CHART, voluntary or due to technical examinations (office action #6.1 or #7.1) that
will expand the subject matter claimed, will infringe the provision of Article 32 of the Brazilian IP Statute and therefore will not be accepted. In these situations, the CLAIM CHART containing such changes will be rejected in its entirety, even if the amendment concerns only some of the claims (or even if it focus on only ONE claim), the technical examination shall be based on the earlier CLAIM CHART. It will be up to the examiner to formulate an opinion with office action #7.1 (opinion notice), communicating clearly the non-acceptance (denial) of the CLAIM CHART presented by incidence of Article 32 of the Brazilian IP Statute, and that the CLAIM CHART to be considered for analysis of the merits of the patent application will be the earlier valid CLAIM CHART submitted.

2.3. What characterizes an addition of claimed subject matter?

The scope of protection claimed when the request for examination of the patent application is filed cannot be extended after this date. At no time after the request examination of the patent application is filed, the examiner may propose in its technical opinion that elements present in the specification and not originally claimed to be included in the CLAIM CHART, if such inclusion will expand the scope of the claimed subject matter. Neither can the applicant take advantage of the compliance of an office action’s requirement to make this inclusion, expanding the scope of the claim. For example, if the object claimed on the date of the request for examination is filed refers to a computer screen, the insertion of elements restricting its scope, such as an insertion of an element that refers to computer screens LCD. The insertion of elements that describe a rotational base for the LCD screen would be accepted, because it restricts the object. However, a new claim modifying the object to a rotational base would not be accepted within the considerations presented in this Rule. Changes in the claims are therefore accepted, provided that it is not noticed an increase of their scope, when compared to what was being claimed when the request for examination was filed.

Elements of an independent claim cannot be withdrawn after the deadline represented by the request for examination of a patent application, as it is not allowed to enlarge the scope of the subject matter claimed in the date said request is filed. Exceptions include the exclusion of: (i) explanatory parts, (ii) matter not considered essential to the description of the invention, (iii) matter not considered to be an invention (according to Article 10 of the Brazilian IP Statute), or (iv) matter that relies outside the scope of the original claim. The removal or alteration of elements contained in the specification of the originally filed application may result in increasing the matter. For example, consider an invention relating to a multi-layer laminated panel and that the specification lists the different arrangements of these layers, one of which has an outer layer of polyethylene. An amendment requested by the Applicant to change the outer layer of polyethylene even to omit it could not be accepted. In any of the two conditions the resulting panel would be quite different from the originally disclosed panel in the original patent application, and thus such amendment would be considered an addition of matter. In another example, consider a claim in which the preamble relates to a mold for the molten steel. The suppression of an essential element in the example cited to reformulate the preamble to molds in general, without restriction for use in molten steel, would be considered a modification that would expand considerably the scope of the original claim and, therefore, a violation of Article 32 of the Brazilian IP Statute.

Amendments to the CLAIM CHART resulting from the compliance with an office action’s requirement or notice of opinion formulated by the Brazilian PTO will be accepted provided that they: (a) restrict a claim, (b) correct an unequivocal clerical error, or (c) clarify an ambiguous description. Therefore, it will be acceptable: i) the removal of an element initially exposed in an alternatively way, ii) the addition in series of elements to an invention, iii) change of a general concept for a specific one, iv) reduction of number of independent claims cited in multBrazilian IP Statute dependent claims, v) the incorporation into an independent claim of an characteristic present in a dependent claim. Considering the aforementioned, it will not be accepted:
i) the exclusion of an invention of the invention described in series, ii) the addition of an element in an alternative way, iii) transfer to a dependent claim of a characteristic originally present in an independent claim.

The following are examples of some of the aforementioned situations:

(1) Consider the following claim: “Device, comprising: a pencil, a rubber attached to an end of the pencil; a luminous effect attached near to the center of the pencil.” If we added an essential element we would have, for example “Device comprising a pencil, a rubber attached to one end of a pencil, a luminous effect attached near to the center of the pencil and a removable cap cover secured to one end of a pencil.” The additional element cap cover restricts the claim, so that now it relates to a smaller set of pencils compared with the scope of the original claim. In this case, as there is restriction of the scope, such modification will be accepted by the Brazilian PTO, either voluntarily or in compliance with an office action’s requirement, although this additional element is not found in any part of the original claims when the exam of the application was performed (even if they relate to an independent or dependent claim). Additions and limitations must be all based on the original specification, otherwise, it will be set up a situation of addition of matter to the original application, what is prohibited by Article 32 of the Brazilian IP Statute and, therefore, such additions will be rejected.

(2) In case of inconsistency between a claim and the specifications, in which a claim is more limited than the description contained in the specification, it is not possible to amend it in order to broaden the scope of the claim. For example, consider a claim that describes a circuit employing semi-conductor devices. However, the specification and drawings always refer to electronic valves. The inconsistency cannot be removed by widening the scope of such claim in such a way to cover both electronic and semi-conductor valves.

(3) Amendments to the CLAIM CHART will be accepted in the case of material and unequivocal errors or as long as they bring some detail or restriction of its scope. Consider the case of a claim that is “wheel characterized by a metallic material”, and in which, at any time, either in the CLAIM CHART or specifications, it is said that this material is titanium. It does not matter if the said omission was intentional or not. The application amendment to include this information will not be accepted, because it is a characterizing and essential part of the invention, configuring, therefore, adding of matter. Consider, in this same example, that titanium is mentioned in the specifications. In this case, a new CLAIM CHART submitted after the date in which the request of examination is filed, which includes in the characterizing part the mention that the said material is titanium would be accepted since it does not modify the object originally claimed but leads to its restriction. The scope of protection of the new claim, beyond the fact of being included in the matter contained in the specification, is fully enclosed in the original claim, and can be considered a subset of it, and therefore is characterized the restriction of the CLAIM CHART. On the other hand, if the new claim plead “wheel characterized by the use of air chamber”, we would not have a restriction of protection, but the modification of the object originally claimed, which now cannot be seen as a subset of it (in view of the fact that the specification does not contain information regarding the air chamber), and thus, such a modification would not be accepted for infringement of Article 32 of the Brazilian IP Statute.

(4) consider the case of a patent application which claims (in valid CLAIM CHART) a “mechanical system characterized by containing among other details a screw”. Then a search based on this information was performed. The documents found in the search refer to the matter of the said application; however, the screw found in the search is of a general and common kind. The examiner issued an unfavorable technical opinion, alleging that all matter claimed was already revealed in the prior art documents cited. In its manifestation, the Applicant submitted a new CLAIM CHART with the information that the mentioned screw has thread on the left, and this information was not initially claimed, although it was disclosed in the specification submitted by the Applicant. From this point, a question would arise whether or not the expansion of matter to be protected,
since the Applicant had not claimed this screw with left hand thread. In our view, when added the information about the thread type (in this case, left) in the new CLAIM CHART, the applicant would be restricting and clarifying the matter claimed, because the term “screw” was so broad and general, and with the information brought to the new CLAIM CHART, it was possible to make the feature more specific, restrictive, in front of the various possibilities of screws found in the prior art. The modification of the CLAIM CHART would be accepted and the examination would proceed and, if necessary, a new complementary search would be performed, paying attention to the detail of the screw with left hand thread.

2.4. Category Changes

Changes of claim category will only be accepted after the request for examination is filed in the following cases:

i) when the original CLAIM CHART contains claims of “product characterized by the process” and the Applicant modify such claim to “process characterized by the process”;

ii) when the original CLAIM CHART contains “process characterized by the product” and the Applicant modify such claim to “product characterized by product” and;

iii) when by a gross error, in case the Applicant has originally requested a claim in the incorrect category. For example, a product defined by steps of a process when the process would be a method claim.

It is understood that, in these cases, the scope of protection originally claimed is not being changed. However, such changes can only be accepted based on the content of the valid CLAIM CHART and not based on what the specification would understand that it is the invention, that is, the valid CLAIM CHART if the “product” is “characterized by the process,” would accept the modification to the process category, but if the CLAIM CHART contains only valid claims “featured product by product” will not be allowed to change the category of “process”, even if the examiner understands, according to the specification, that the invention would be the process. The following situations exemplify, in a non-exhaustive manner, the points mentioned above:

(1) If the CLAIM CHART, on the date of request for examination of a patent application is filed, claims a chemical compound with characteristics of a compound and subsequently amendments are submitted claiming a composition or kit, these will not be accepted for violation of Article 32 of the Brazilian IP Statute. However, if the valid CLAIM CHART claimed a chemical compound characterized by a composition, so in this case a later amendment claiming composition will be accepted. If the valid CLAIM CHART claimed a product characterized by the process, subsequent amendments claiming that referred process will be accepted. On the other hand, if the valid CLAIM CHART claimed a product characterized by the process, subsequent amendments claiming the product with characteristics of product will not be accepted. If the valid CLAIM CHART claimed a pharmaceutical formulation, subsequent amendments claiming the pharmaceutical composition will be allowed.

(2) With respect to the modification of claims of therapeutic method to claims of the “Swiss formula” type, it is understood that the scope of a claim of therapeutic method is quite distinct from the scope of a claim of “use of a compound X to prepare a medicine for treating a disease” as the first provides a method of treatment to the individual, while the second refers to the application of an active substance in the preparation of a medicine for treating a specific disease. Therefore, in the light of Article 32 of the Brazilian IP Statute claims change of therapeutic method for claims drafted along the lines of “use of a compound X for preparing a medicament for treating a disease” (Swiss formula) will not be admitted after the date the request of examination was filed, since such amendment clearly modifies the object contained in the valid CLAIM CHART.

(3) If a valid CLAIM CHART claimed a “derivate iron-dextran characterized in that is prepared from ferric hydroxide formed in situ by mixing dextran with an iron salt (III) adjustment to an alkaline pH and heating” the modification of said claim to “Process for preparing derivatives of iron dextran characterized by steps: i)”
mixing dextran with an iron salt (III), ii) adjusting to alkaline pH with NaOH and iii) heating at 100°C to form ferric hydroxide in situ” will be accepted, since it is understood that the original scope was the process of preparation and, therefore, the claimed object was not changed.

(4) For inventions implemented by computer program, considers for example, a claim of product in terms of their structural characteristics: “Control device of automatic clutch characterized by a reference generator of responsive sliding to the acceleration signal, a circuit to produce error signal, a PID regulator”. An amendment made after the date of the request for examination is filed claiming the method in its functional characteristics implemented by this device would not be accepted for violation of Article 32: “Method for automatic clutch controlling characterized by steps of measuring the engine speed, generating a slide reference signal, comparing engine speed and input speed, control clutch actuation”.

(5) On the other hand, even in the case (4), consider a product claim described in its functional characteristics: “Automated mechanical system to control a gears change transmission comprising a fuel choker, a mechanical transmission of gear change characterized in that it comprises: i) means for detecting the effective gear ratio used during each start operation, ii) means for memorize the effective gear ratio used during each start operation”. In this case, amendments made after the date of the request of examination was filed that will describe the method that was previously contained in the product claim, are not understood as a violation of Article 32 and would be accepted; Thus, it would be admitted: “Method for controlling a gears change transmission mechanical automated system comprising a fuel choker, a mechanical transmission of gear change characterized in that it comprises: i) detecting the effective gear ratio used during each start operation, ii) memorizing the effective gear ratio used during each start operation”. This situation wherein the method claim is embodied in the product by the functions claim is an exception to the general rule that considers category changes in violation of Article 32 provisions of the Brazilian IP Statute, since in this particular case in the two categories the contribution to the prior art resides in the method itself.

(6) For inventions implemented by computer programs, framing the object of the patent in the exceptions provided in Article 10 of the Brazilian IP Statute is not dependable from the claim category, that is, independently of claim is a process or a product for performing the process, this product being characterized by steps of the said process. Thus, amendments in the valid CLAIM SET would be accepted even they involve changing in the originally contested category, as in any case, prevails the not patentable because of the incidence on Article 10 provision of the Brazilian IP Statute. For example, in case a patent application related to an implemented invention by computer program that has a claim of financial method, this invention is not according to Article 10 provisions - paragraph III of the Brazilian IP Statute. An amendment into the CLAIM SET which contest physical support (CDROM, ROM, etc.) characterized by this financial method, likewise does not constitutes an invention under Article 10 - paragraph III of the Brazilian IP Statute, because the contribution to the prior art still remain in the area framed in Article 10. In the case wherein a method is considered an invention, change or addition to the category “Support characterized by physical method” is not regarded as violation of article 32 of the Brazilian IP Statute.

(7) Consider a patent application claiming a process wherein some technical characteristics are claimed, for example, related to the transmission of mixed data with a financial method steps. If it is determined that the steps for financial method are not essential to achieving the object claimed, that is, if the object of the invention is maintained without the steps for financial method, then this process can be considered an invention. In this case, the amendments in claims which withdraw this additional matter considered to be incident on Article 10 of the Brazilian IP Statute would be capable of being performed without configuring violation of article 32 of the Brazilian IP Statute.

(8) Consider an application that claims a “device to intra-corneal implant comprising a solid or gelatinous body having a biocompatible polymer, characterized in that its outer surface is coated by a mucous-polysaccharide,
wherein said device is inserted into the corneal intimacy through a laser-incision tunnel-shaped”. The element “where said device is inserted into the corneal intimacy of the through a laser-incision tunnel-shaped” clearly refers to an operating method, which is not considered an invention according to Article 10 (VIII) of the Brazilian IP Statute. Thus, the amendments in claims which withdraw this additional matter considered to be incident on Article 10 of the Brazilian IP Statute, may also be performed without configuring violation to article 32 of the Brazilian IP Statute.

2.5. CLAIM SET that focus on Article 32 of the Brazilian IP Statute will be refused entirely

When a CLAIM CHART submitted by the Applicant (even those CLAIM CHART presented in a reply to a technical examination opinion) is contrary to Article 32 of the Brazilian IP Statute, it will be rejected in its entirety, and not partially. As previously established, it doesn’t matter if the problem is only in one (01) claim. The CLAIM CHART shall be rejected in its entirety, returning the exam to the previous CLAIM CHART. Thus, the examination should comprise an indication that the new CLAIM CHART was not accepted as a result of the application of the provision of Article 32. That is, the examiner shall always point out which claims fell under the provisions of Article 32 and, therefore, led to the rejection of the full CLAIM CHART. In these cases, the exam will be based on the earlier CLAIM CHART and the conclusions will be presented in regards to the examination of the merits of the earlier CLAIM CHART.

Even in cases where a CLAIM CHART is denied by application of the provisions of Article 32 of the Brazilian IP Statute, the examiner should always evaluate whether the denied CLAIM CHART contains matter capable of being granted that can be used as subsidy and/or that may direct the exam of the earlier CLAIM CHART, for procedural economy.

In the 2nd instance, apply the same procedures likewise 1st instance.

2.6. Timeframe for the analysis of Article 32 of the Brazilian IP Statute in regard to Divisional Applications shall be the date of the request for examination of the Original Patent Application

In the case of the analysis of patent applications resulting from the division of an Original Application (divisional applications), this will be done based on a valid CLAIM CHART submitted by the Applicant until the date the request for examination of the original patent application (or the CLAIM CHART submitted with this petition, if any) is filed. Note that the concept of Original Application refers to the patent application that originated the first Divisional Application. If after the date in which the request for examination of the Original Patent Application was filed the Applicant files a request for division of the application, it is understood that it will be a valid, for the purposes of verification of the provision of Article 32 of the Brazilian IP Statute of the Divisional Application’s CLAIM CHART, the CLAIM CHART submitted by the Applicant until the date in which the request for examination of the Original Application (or CLAIM CHART submitted with this petition, if any) was filed.

2.7. Harmony between Article 26 and Article 32 of the Brazilian IP Statute was established in Order #08/2010, of the Chief Attorney, Mauro Maia.

According to the order #08/2010 “patent applications that result from the division in accordance with article 26 of the Brazilian IP Statute, when this occur after the request for examination of the Original patent application, will be subject to the time limit laid down in Article 32 Brazilian IP Statute, that is, its CLAIM CHART will not be changed by volunteer amendments”.
According to Article 26, patent application division will have its acceptance based on the subject matter initially disclosed. Once completed the requirements in Article 26, the division of the patent application will be accepted. However, the divisional application’s CLAIM CHART will be reviewed at the time of its technical examination, considering Article 32 provisions of the Brazilian IP Statute: If the patent application division occurs AFTER the request for examination of the Original Application, the CLAIM CHART of the Divisional Application SHALL BE RESTRICTED TO THE CLAIMED MATTER in the valid CLAIM CHART when the request for examination of the Original Application was filed, even if such claims are based on matter disclosed in the Original Application. Hereinafter, we will apply the decisions already made in this Rule related to CLAIM CHART acceptance, considering the provisions of Article 32 of the Brazilian IP Statute.

**PART 3**

**PROCEDURES FOR IMPLEMENTATION OF THE ARTICLE 32 PROVISIONS OF THE BRAZILIAN IP STATUTE IN PATENTS APPLICATIONS EXAMINATIONS**

It was elaborated three diagrams, as follows (the graphical representation of the diagrams is found in Part 4 of this Rule):

(i) Case 01: 1st Technical Examination;
(ii) Case 02: 2nd Technical Examination and Further Examinations
(iii) Case 03: Divisional Applications;

The situations mentioned below aim exclusively to direct the technical examination in regard to procedures to be adopted in case of incidence of Article 32 of the Brazilian IP Statute. Verified such situation and applied the guidelines of this Rule, the technical examination will proceed considering the Patent Division – Board of Directors examination guidelines.

**3.1. CASE 01: INCIDENCE OF ARTICLE 32 OF THE BRAZILIAN IP STATUTE IN THE FIRST TECHNICAL EXAMINATION**

The diagram (see Figure 1 - PART 4 of this Rule) has as its starting point a “valid claim chart”. This designation refers to the claim chart submitted by the Applicant until the date in which the request for examination of the patent application (or claim chart attached to this petition, if any). From this claim chart, two situations are presented:

(1) The Applicant has not submitted a new claim chart after the filing date of the request for examination of the patent application, and
(2) The Applicant submitted a new claim chart after the filing date of the request for examination.

In situation (1), the exam will follow in accordance to Board of Directors’s examination guidelines. In situation (2), the new claim chart will be analyzed to obtain the perception regarding the compliance with the rules set out by Article 32 of the Brazilian IP Statute. Four situations are predicted:

(2.i) Changes corresponding to correct spelling and/or translation of the valid claim chart;
(2.ii) Changes corresponding to restriction of the subject matter claimed in a valid claim chart (according to criteria set out in Part 2 of this Rule);
(2.iii) Changes corresponding to the enlargement of the scope of protection initially claimed in the valid claim chart (according to criteria set out in Part 2 of this Rule);
(2.iv) Changes corresponding to categories modification or claim types in discordance to valid set claim (according to criteria set out in Part 2 of this Rule).
In cases (2.i) and (2.ii), changes would be accepted and the technical examination will follow in accordance with the examination guidelines of Board of Directors.

Cases (2.iii) and (2.iv), however, represent situations whose changes are not allowed in accordance to decisions discussed in PART 2 of this Rule, and thereby, the new claim chart must be rejected in its entirety. The examiner, in its technical opinion, will refer to the rejection of the new claim chart for infringing Article 32 of the Brazilian IP Statute, and will perform the technical examination considering the valid claim chart. In this case, it will be evaluated the hypothesis of the patent application (including the valid claim chart) be able to obtain the desired patentability. If the valid claim chart is not able to obtain patentability, the examination will occur in accordance to examination guidelines of Board of Directors. However, if the valid claim chart conform with the patentability requirements (and patent application, as a whole, meets the condition to be granted), the examiner shall issue a technical opinion (office action #7.1), communicating the applicant that the new claim chart was rejected by incidence of Article 32 of the Brazilian IP Statute and the valid claim chart is the one which is able to obtain patentability. This fact is important, since that the Applicant cannot has the grant established in relation to a claim chart other than the one he would desire (it must be given to the Applicant the right to manifest himself in regards to the rejection of the new claim chart).

In case the Applicant, in its manifestation about the technical opinion #7.1, persists with the amended claim chart (rejected under Article 32 of the Brazilian IP Statute) and his arguments (Applicant) are considered non-persuasive by the examiner, the patent application should be rejected in accordance to Article 32 of the Brazilian IP Statute.

3.2. Case 02: Incidence of Article 32 of the Brazilian IP Statute in the second technical examination and subsequent examinations

The diagram presented below (see Figure 2 - PART 4 of this Rule) has as its starting point the petition which presents the “Manifestation of the Applicant to a technical examination (office actions #6.1 or #7.1)”. From this petition two situations are presented:

(1) The Applicant has not submitted a new claim chart in its manifestation, and
(2) The Applicant submitted a new claim chart in its manifestation. In situation (1), the exam will occur according to Board of Directors’s examination guidelines. In situation (2) the claim chart will be analyzed with regard to the proposed amendments, considering the provisions of Article 32 of the Brazilian IP Statute. Four situations are predicted:
   (2.i) The changes correspond to correcting spelling and/or translation of the previously analyzed claim chart (valid claim chart);
   (2.ii) The changes correspond to restriction of the subject matter claimed in the valid claim chart (according to criteria set out in Part 2 of this Rule);
   (2.iii) The changes correspond to the enlargement of the scope of protection claimed initially in valid claim chart (according to criteria set out in Part 2 of this Rule);
   (2.iv) The changes correspond to modification in the category or claim types in comparison to the valid claim chart (according to criteria set out in Part 2 of this Rule).

In cases (2.i) and (2.ii), the changes will be accepted according to Part 2 of this Rule: the new claim chart will be accepted and the technical examination will occur in accordance to examination guidelines of Board of Directors.

Cases (2.iii) and (2.iv), however, represent situations in which changes are not allowed, according to the guidelines
contained in PART 2 of this Rule, and thereby, the new claim chart will be rejected in its entirety. In this case, two situations must be considered:

(3.i) The claim chart considered in the previous examination was not rejected under the provisions of article 32 of the Brazilian IP Statute;
(3.ii) The claim chart considered in the previous examination was rejected under the provisions of article 32 of the Brazilian IP Statute.

In situation (3.i), the new claim chart shall be rejected in its entirety and the examiner will perform the exam considering the earlier claim chart, and a technical opinion will be issued (office action #7.1) notifying about the rejection of the new claim chart in its entirety under Article 32 of the Brazilian IP Statute.

In situation (3.ii), there has been a notification in the previous technical opinion in regard to the incidence of article 32 of the Brazilian IP Statute. Once the Applicant has already been notified about the subjection of the application under analysis to the provisions of article 32 of the Brazilian IP Statute, it is understood that the right to adversarial procedure has already been granted to the Applicant. Thus, there is no need to notify the Application one more time in regard to this non-compliance. Consequently, the patent application will be denied (office action #9.2), in view of the reasons for non-patentability pointed out in the technical opinion of the previous examination and, additionally, under article 32 of the Brazilian IP Statute.

3.3 Case 03: Incidence of Article 32 of the Brazilian IP Statute in Divisional Applications

The diagram presented below (see Figure 3 - PART 4 of this Rule) has as its starting point a “valid claim chart - Original Application”. This designation refers to the claim chart submitted by the Applicant until the date of the request for examination of the original patent application (or claim chart filed with this petition, if any). From this valid claim chart, two situations may be presented:

(1) The claim chart of the Divisional Application does not violate the provision contained in Article 32 of the Brazilian IP Statute, and
(2) The claim chart of the Divisional Application contains changes that violate the provision contained in Article 32 of the Brazilian IP Statute.

In situation (1), the examination of the Divisional Application will proceed in accordance with Board of Directors’s examination guidelines. In situation (2), the Divisional Application’s claim chart will be analyzed according to one of the two situations described below:

(2.1) The request for the division of the patent application (Divisional Application) was made BEFORE the first examination of the Original Application;
(2.ii) The request for the division of the patent application (Divisional Application) was made AFTER the first examination of the Original Application, and the result of said exam was a notification of technical opinion (office action #7.1).

In the cases provided for in (2.ii) it shall be issued a notification of issuance of a technical opinion (office action #7.1) for the Divisional Application, informing the Applicant that said application’s claim chart was rejected because it contradicts the provisions of Article 32 of the Brazilian IP Statute.
In the cases provided in (2.2), two situations must be observed:

(3.i): The claim chart of the Original Application did not present objections in regard to the provisions of Article 32 of the Brazilian IP Statute;
(3.ii): The claim chart of the Original Application presented objections in regard to the provisions of Article 32 of the Brazilian IP Statute;

In situation (3.i), it shall be issued a notification of issuance of a technical opinion (office action #7.1) for the Divisional Application, notifying the Applicant that said application's claim chart was rejected because it contradicts the provisions of Article 32 of the Brazilian IP Statute.

In situation (3.ii), since there already have been violations of the Original Application in regard to the provisions of Article 32 of the Brazilian IP Statute, and considering that the Divisional Application is on the same procedural phase of the Original Application (according to item 6.6 of Rule PR #17/2013), the patent application must be denied, based on the provisions of Article 32 of the Brazilian IP Statute.

In case of Divisional Applications, the examiner should pay attention to the date in which the division of the application was requested, and also to observe if in the technical opinion issued for the Original Application it was mentioned the objection under Article 32 of the Brazilian IP Statute before its division.

The Brazilian IP Statute provides that when a technical opinion for a patent application in which were pointed out objections to the patentability of the claimed object is issued, the Applicant will have 90 days to manifest himself. Suppose that in this technical opinion there is no citation of objections under Article 32 of the Brazilian IP Statute. The Applicant then manifest himself presenting a new claim chart that, now, falls under the provisions of Article 32 of the Brazilian IP Statute. However, before the manifestation submitted for Original Application is analyzed and gets its technical opinion published on the BRPTO Official Gazette, the Applicant files a Divisional Application whose claim chart falls under Article 32 of the Brazilian IP Statute as well (this incidence was based on the valid claim chart of the Original Application). In this case, the analysis of the Divisional Application will indicate that the claim chart shall be rejected under Article 32 (when it is compared with the valid claim chart of the Original Application). The adversarial principle of the Brazilian IP Statute shall be observed and, thus, a technical opinion of the examination of the Division Application shall be issued containing a notification of the issuance of said technical opinion (office action #7.1), based on Article 32 of the Brazilian IP Statute.

3.4. CASE 04: INCIDENCE OF ARTICLE 32 OF THE BRAZILIAN IP STATUTE IN THE EXAM OF PATENT APPLICATIONS ON APPEAL

Article 212, ¶ 1, of the Brazilian IP Statute provides that appeals will be accepted are given full suspensive and devolutive effects and that all pertinent provisions to the first instance examination are applicable, when compatible.

Thus, the deliberations of this Rule will be applied, when compatible, to the analysis of patent applications in the second instance.
Diagram related to procedures regarding application of Article 32 in the first technical examination.

Valid Claim Chart

1. The applicant did not submit a new claim chart after request for examination (#31 of the patent workflow)
   - Spelling or translation
   - Restriction of the claim chart
   - Accepted
   - Proceed with the technical examination

2. The applicant did submit a new claim chart after request for examination (#31 of the patent workflow)
   - Amendment of the claim chart aiming to broadening the scope of the subject matter originally claimed
   - Modification of the categories initially claimed
   - Reject of the entire claim chart as it does not comply with Article #32 BRPTO will examine the previous claim chart
   - Previous claim chart presents conditions for allowance
   - No
     - Office action #7.1 (technical opinion) notifying that the claim chart was rejected due to non-compliance with Article #32 and that the previous claim chart is able to be allowed
   - Yes
Applicant reply (Office action #6.1/#7.1)

- Reply without new claim chart
  - Spelling or translation correction
    - New claim chart accepted
      - Proceed with the technical examination
  - Restriction of the claim chart
  - Amendment of the claim chart with broadening of the initially claimed
    - Was the previous claim chart rejected due to non-compliance with Article #32?
      - Yes
        - New claim chart entirely rejected and issuance of opinion with office action #9.2 (not allowed)
      - No
        - New claim chart entirely rejected and issuance of office action #7.1 (technical opinion)
- Reply with a new claim
  - Restriction of the claim chart
  - Amendment of the claim chart with broadening of the initially claimed
    - New claim chart entirely rejected and issuance of office action #7.1 (technical opinion)
Fig. 3 – Diagram related to procedures regarding application of Article 32 in Divisional Applications

- **Valid Claim chart for the parent Application**
  - **Divisional application complies with Art. 32 (no amendments)**
  - **Divisional filed before the first examination of the parent Application**
    - **Claim chart of the parent Application complies with Article #32 (no amendments)**
      - **Office action #7.1 (technical opinion) on the divisional Application due to non-compliance with Art. 32**
      - **Proceed with the technical examination**
  - **Divisional filed after the examination of the parent Application**
    - **Claim chart of the parent Application does not comply with Article #32 (with amendments)**
      - **Reject the divisional Application based on Art. 32**
  - **Divisional application does not comply with Article #32 (with amendments)**
    - **Reject the divisional Application based on Art. 32**
## Examples of the Application of the Provisions of Article #32 of the Brazilian IP Statute in Some Areas of the Brazilian PTO’S Patent Division – Board of Directors

<table>
<thead>
<tr>
<th>#</th>
<th>Protection originally claimed</th>
<th>Changes</th>
<th>Submitted ON or BEFORE the request for examination</th>
<th>Submitted AFTER the request for examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Compound with compound characteristics</td>
<td>Composition</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kit</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>2.</td>
<td>Compound characterized by a composition</td>
<td>Composition</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>3.</td>
<td>Composition</td>
<td>Kit</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>4.</td>
<td>1. Compound with compound characteristics 2. Process characterized by process</td>
<td>Compound with compound characteristics</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Process characterized by process</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Composition with composition characteristics</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Compound with process characteristics</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>5.</td>
<td>Product characterized by process</td>
<td>Only product characterized by process</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product characterized by process</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Only process with process characteristics only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Product with product characteristics only - by Process</td>
<td>YES</td>
<td>NO to the product and YES for the process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product with product characteristics only</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>7.</td>
<td>Process characterized by product</td>
<td>- Product with product characteristics - Process characterized by process</td>
<td>YES</td>
<td>YES for the product and NO to the process</td>
</tr>
<tr>
<td>8.</td>
<td>Process and product characterized by process</td>
<td>Product with product characteristics only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product with product characteristics only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Process characterized by process only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Product characterized by product - Process characterized by process</td>
<td>YES</td>
<td>NO to the product and YES for the process</td>
</tr>
<tr>
<td>#</td>
<td>Protection originally claimed</td>
<td>Changes</td>
<td>Submitted ON or BEFORE the request for examination</td>
<td>Submitted AFTER the request for examination</td>
</tr>
<tr>
<td>----</td>
<td>-------------------------------</td>
<td>---------</td>
<td>--------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>9.</td>
<td>Process characterized by process and product</td>
<td>Process characterized by process only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product with product characteristics only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Product with product characteristic</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Process with process characteristics</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>10.</td>
<td>Process with process characteristics</td>
<td>Product with product characteristics</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>11.</td>
<td>Therapeutic Methods</td>
<td>Use to prepare (Swiss formula)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>12.</td>
<td>Therapeutic Methods</td>
<td>Composition</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>13.</td>
<td>Process to obtain characterized by steps</td>
<td>Use to prepare (Swiss formula)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Use (application)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>14.</td>
<td>Therapeutic Methods</td>
<td>Dosage form</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>15.</td>
<td>Process comprising heating step from 100 to 1000 C</td>
<td>Process comprising heating step from 300 to 800 C</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>16.</td>
<td>Process comprising heating step from 100 to 1000 C</td>
<td>Process comprising heating step from 5 to 1000 C</td>
<td>YES</td>
<td>NO (since it is not a typing error)</td>
</tr>
<tr>
<td>17.</td>
<td>Obtaining process</td>
<td>Production method</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>18.</td>
<td>Obtaining process</td>
<td>Application method</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>19.</td>
<td>Process</td>
<td>Apparatus</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>20.</td>
<td>Use (ex. Use as insecticide; i.e. applicability)</td>
<td>Use to produce</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>21.</td>
<td>Host cell</td>
<td>Micro-organism/bacterium/yeast</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>22.</td>
<td>DNA segment defined as probe</td>
<td>Probe/initiator</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>23.</td>
<td>DNA segment</td>
<td>Probe/initiator</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>24.</td>
<td>Vector</td>
<td>Expression vector</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>25.</td>
<td>Extract*</td>
<td>Composition defined qualitative/quantitative</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>26.</td>
<td>Extract characterized by obtaining process</td>
<td>Process characterized by obtaining process</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>27.</td>
<td>Pharmaceutical Formulation</td>
<td>Pharmaceutical composition</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>28.</td>
<td>Dosage form</td>
<td>Article of manufacture or kit</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

“Extracts comprise, except in very rare cases, several active and non-active compounds”
The Brazilian FDA rules on prior approval of pharmaceutical patents

Brazilian FDA Rule RDC #45/2008, as amended by Rule RDC #21/2013, in respect of the prior approval under Article 229-C of Patent Statute #9,279, as amended by Statute #10,196.
The BRFDA's Board of Directors, by the power invested in them by item IV of article 11 of the Rule approved by Executive Order #3,029, of April 16, 1999, and given the provisions of item II and paragraphs 1 and 3 of article 54 of the Internal Guide Rule approved in the terms of Annex I of BRFDA's Ordinance #354, of August 11, 2006, republished in the Official Gazette of August 21, 2006, in the meeting held on June 17, 2008, and:

Considering that the direct and indirect public administration of any of the Powers of the Union, States, Federal District and Municipalities will obey the principles of legality, impersonality, morality, publicity and efficiency, pursuant to Article 37 of the Federal Constitution of 1988;

Considering that the public administration will also obey, amongst others, the principles of purpose, motivation, reasonability, proportionality, full-defense, due process system, vested rights and public interest, pursuant to Article 2 of Statute #9,784, of January 29, 1999, regulating the administrative proceedings within the Federal Government, seeking, especially, the protection of the rights of the administered and the better execution of the Administration's purposes;

Considering that the BRFDA's activity must be judicially conditioned by the principles of validity, celerity, finality, reasonability, impersonality, impartiality, publicity, morality and economical proceedings, pursuant to Article 29 of its Rule approved by Executive Order #3,029, of April 16, 1999;

Considering the dispositions of the Agreement on Trade Related Aspects of Intellectual Property Rights – TRIPS – of the World Trade Organization, especially where it refers to the right of the members of organizing themselves administratively in their best judgment for the execution of the Agreement;

Considering the BRFDA's institutional purpose of promoting the protection of the population's health and its legal attributions established in Statute #9,782, of January 26, 1999;

Considering that the granting of patents of pharmaceutical products and processes by the Brazilian PTO – INPI depends on prior approval from the BRFDA, pursuant to article 229-C of Statute #9,279, of May 14, 1996, that regulates rights and obligations in industrial property, as amended by Statute #10,196, of February 14, 2001;

Considering the guidelines, the priorities and the responsibilities established in the National Medicine Policy established by the Ordinance #3,916/MS/GM, of October 30, 1998, that seeks to guarantee conditions for the safety and quality of the medicines consumed in the country, promote the reasonable use and the population's access to those considered essential;

Considering the Rule #338, of May 6, 2004, of the National Counsel for Health, that approves the National Policy of Pharmaceutical Assistance of the Ministry of Health; and

Considering the need to improve the procedure of prior approval of the BRFDA for the granting of patents for pharmaceutical products and processes, decides to adopt the following Rule of the Full Board of Directors and I, Director-President, determine its publication:

**Article 1.** The BRFDA's prior approval for the granting of patents for pharmaceutical products and processes is subject to the rules and procedures established in this Rule and other rules in force.

**Sole ¶.** The disposition established in this article applies to the applications for patents of invention of pharmaceutical products and processes that on December 15, 1999, were in course or were filed from that date on before the Brazilian PTO.
Article 2. For the purposes of this Rule the following definitions are adopted:
I. prior approval: the BRFDA's deliberative act issued taking into account the compliance regarding article 229-C of Brazilian IP Statute #9,279, 1996, in which the Agency must verify if the object of the patent application is against public health;
II. applicant: any individual or company that filed a patent application before the BRPTO;
III. interested party: any person, individual or company, that holds interest, pursuant to Statute #9,784, of 1999, or that holds relevant information for the examination of a patent application;

Article 3. The prior approval process will take place with the sending by the BRPTO of the application to the BRFDA for acknowledgement and manifestation, and the BRFDA may make an informed conclusion regarding approval.

Article 4. After receiving the patent application sent by the BRPTO, the BRFDA will perform its examination in light of public health, through a decision in the technical opinion submitted by competent area department inside the the BRFDA.

¶1. The patent application shall be considered against public health when:
I. The pharmaceutical product or process in the patent application presents risk to health; or
II. The patent application of pharmaceutical product or process is of interest to the public policies of access to medicines and pharmaceutical assistance of the National Healthcare System (SUS) and does not meet patentability requirements and further criteria established by Patent Statute #9,279 of 1996.
¶2. The risk to health will be characterized when the pharmaceutical product comprises, or the pharmaceutical process results in, substance which the use may have been prohibited in Brazil.
¶3. The patent application for pharmaceutical product or process will be deemed as interest to the public policies of access to medicines and pharmaceutical assistance of the National Healthcare System (SUS) when it comprises, or results in, substance established in the Ordinances published by the Ministry of Health establishing the strategic products, for the National Healthcare System, and its regular amendments, as well as comprising, or resulting in, substance established to the therapeutic purpose listed in the mentioned Ordinances.
¶4. The guidelines for the analysis of risk to health and interest to the public policies of access to medicines and pharmaceutical assistance of the National Healthcare System will be established in the proper act.
¶5. The applicant shall submit to the BRFDA, whenever requested, all the necessary documents to answer the questions raised during the examination.
¶6. Until the end of the examination mentioned by this Rule, the interested parties will be able to submit documents and other information to assist the BRFDA's examination.

Article 5. When the technical report states, preliminarily, for the denial of the prior approval or formulates any office action, the applicant or their legal representative will be notified through registered letter, to reply, within ninety days, starting from the date of the official notification or from the notice given to the interested party in the proceeding.

¶1. If a reply to the office action is filed, even if it is not fulfilled, or if its formulation is objected, having or not any manifestation concerning its merits, the BRFDA shall proceed with the analysis.
¶2. Prior approval will not be granted to patent applications having an unreplied office action.

Article 6. When the assessment performed within the BRFDA concludes for approval, the application will return to the BRPTO for the conclusion of the patent granting proceeding. (revoked)

Article 7. The decisions concerning the conclusion of the prior approval examination will be published in the Brazilian Official Gazette.
¶1. An appeal to the Full Board of Directors of the BRPTO can be filed within sixty days against the decision that denies the prior approval to the application, pursuant to article 15, paragraph 2, of Statute #9,782, of 1999, article 11, ¶1, of Executive Order #3,029, of April 16, 1999, art. 212 of Statute #9,279, of 1996, complying with the specific regulation that establishes the proceedings of administrative appeals within the BRFDA.

¶2. After the BRFDA's final decision, the application shall return to the BRPTO for administrative proceedings conclusion.

Article 8. The petitions and documents dealt by this Rule shall be received according to the specific regulation on the BRFDA's protocol.

Article 9. This Rule will enter into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO