

2016APAA Patents Committee Questionnaire
Patent Eligibility – To Be or Not To Be

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Introduction

Patent eligibility is, without doubt, a fundamental requirement whether to confer an exclusive right or not with respect to an invention. Patent eligibility is also functions as a gatekeeper or threshold to proceed to further patentability questions such as novelty/inventive-step, because technically neither the novelty nor inventive-step is examined unless the patent eligibility is satisfied.

Anticipating substantial diversity in the patent eligibility among APAA countries, this year we will attempt to identify the similarities and differences in the laws and practices in various APAA countries, and underlying rationale thereof.

Following questionnaire falls into general questions which is universally applicable (A), questions peculiar to specific technical field(s) (B) and questions about history (C).

A: General

A1(Eligibility)

(1) Do you have any Laws, Regulations, Rules or Guidelines prescribing patent eligibility (subject matter) in your country?

Yes (X) No ()

Reason and/or Basis:

Republic Act 8293: AN ACT PRESCRIBING THE INTELLECTUAL PROPERTY CODE AND ESTABLISHING THE INTELLECTUAL PROPERTY OFFICE, PROVIDING FOR ITS POWERS AND FUNCTIONS, AND FOR OTHER PURPOSES (RA 8293)

THE REVISED IMPLEMENTING RULES AND REGULATIONS FOR PATENTS, UTILITY MODELS AND INDUSTRIAL DESIGNS (IRR)

(2) Are there any criteria for determining patent eligibility?

Yes (X) No ()

Reason and/or Basis:

1. The invention must relate to any of the following categories :

- a. a product, such as a machine, a device, an article of manufacture, a composition of matter, a microorganism, a computer-related products**
- b. a process, such as a method of use, a method of manufacturing, a non-biological process, a microbiological process, a computer related process**
- c. an improvement in any of the foregoing.**

Basis: Section 21 of R.A. 8293 and Rule 201 of the IRR

2. The invention must not fall under any of the following non-patentable inventions:

- a. Discoveries, scientific theories and mathematical methods, a law of nature, a scientific truth, or knowledge as such;***
- b. Abstract ideas or theories, fundamental concepts apart from the means or processes for carrying the concept to produce a technical effect;**
- c. Schemes, rules and methods of performing mental acts, playing games**
- d. Method of doing business, such as a method or system for transacting business without the technical means for carrying out the method or system;**
- e. Programs for computers;**
- f. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods;**
- g. Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to microorganisms and non-biological and microbiological processes.**
- h. Aesthetic creations; and**
- i. Anything which is contrary to public order or morality, health, welfare, or morality, or process for cloning or modifying the germ line genetic identity of humans or animals or uses of the human embryo.**

***In the case of drugs and medicines involving known substances, please refer to the Implementing Rules and Regulations of Republic Act 9502, otherwise known as the “Universally Accessible Cheaper and Quality Medicines Act of 2008”.**

Basis: Section 22 of RA 8293 and Rule 202 of IRR

(3) Does your Laws, Regulations or Rules define the statutory invention?

Yes () No ()

Reason and/or Basis:

Patentable Inventions. — Any technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable shall be patentable.

Basis: Section 21 of R.A. 8293 and Rule 200 of IRR

A2 (Utility and Industrial Applicability)

(1) Are there any stipulations in Laws, Regulations, Rules or Guidelines for rejecting the invention which has no utility?

Yes () No ()

Reason and/or Basis:

(2) If “No,” is utility required for an invention to be protected?

Yes () No ()

Reason and/or Basis:

Under the New IP Code of 1998, the criteria for patent eligibility has shifted from utility to industrial applicability

(3) Are there any stipulations in Laws, Regulations, Rules or Guidelines for rejecting the invention which has no industrial applicability?

Yes (X) No ()

Reason and/or Basis:

Industrial applicability must be satisfied before assessing the novelty and inventive step criteria under Sec. 21 of R.A. 8293.

(4) If “No,” is industrial applicability required for an invention to be protected?

Yes () No ()

Reason and/or Basis:

A3 (Public Interest)

(1) Are there any stipulations in Laws, Regulations, Rules or Guidelines for unpatentable inventions because it contravenes public order or morality, or it injures public health, notwithstanding the eligibility being satisfied?

Yes (X) No ()

Reason and/or Basis:

See Rule 202(i) of IRR above

(2) Are there any stipulations in Laws, Regulations, Rules or Guidelines for unpatentable inventions in order to protect a specific field of domestic industry?

Reason and/or Basis:

Excerpt from Republic Act 9502 QUAMA Guidelines “Section 26 of the IP Code, as amended, states that:

26.1 An invention involves an inventive step if, having regard to prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention.

26.2 In the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant. “For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance, shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy.

To have a meaningful interpretation of this QUAMA provision during substantive examination, there are three (3) cases contemplated namely:

- (a) the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance;
- (b) the mere discovery of any property or new use for a known substance; and
- (c) the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

The three cases enumerated above become material during non-patentable subject matter inquiry and assessment of inventive step requirement of drugs and medicines. The Doctrine of Inherency is adopted to articulate on the meaning of “mere discovery”. Inherent new form or new use of a known substance would be considered as mere discoveries, hence not a patentable subject matter within the purview of the QUAMA provision. A mere use of known process not resulting to a new product and not employing at least one new reactant is also considered as inherent, hence not a patentable subject matter in view of the QUAMA provision.

A new property may be attributed to its new form. The “enhanced efficacy” criterion qualifies “non obviousness” principles in the pharmaceutical field. A new use of a known compound maybe based on the recognition of a previously unknown property of a compound, such property-providing a valuable new technical effect and involving inventive contribution to the art. Where the new technical effect is found to be inherent in the prior art, an objection under Section 22.1 may be made. On the other hand, a new use of a known substance which is not inherent in the prior art would be a patentable subject matter. However, while it may pass the query on “non patentable subject matter,” it shall still be subject to the inventive step criterion.

The examples used in this guideline are illustrations of the doctrine of inherency under the QUAMA provision. Objective decision may be taken by the examiner taking into account the merits of each application.”

Note: R.A. 9502An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or The Intellectual Property Code, Republic Act No. 6675 (also known as QUAMA)

- (3) Are there any stipulations in Laws, Regulations, Rules or Guidelines for unpatentable inventions due to national defense or security?

NONE

Reason and/or Basis:

A4 (Novelty/Inventiveness)

Is the determination of patent eligibility influenced by the assessment of Novelty or Inventiveness of invention? (Shall eligible subject matter include novelty and inventive concept?)

Yes () No ()

Reason and/or Basis:

Generally, novelty and inventive step are assessed after a patentable subject matter is identified.

However, in the case of medicines falling under the QUAMA provision, novelty appears to be a requirement in order for certain forms of substances may be considered as a patentable subject matter. (See above excerpt from the QUAMA Guidelines)

B: Eligibility on Specific Technical Field

B1 (Field Specific Criteria)

Is there any determination Criteria Peculiar to Specific Technical Field? If yes, please enumerate the applicable technical field(s).

Yes (**X**) No ()

Reason and/or Basis:

1. Programs for computers: A computer program claimed by itself or as a record on a carrier, is not patentable irrespective of its content. The situation is not normally changed when the computer program is loaded into a known computer. If however the subject-matter as claimed makes a technical contribution to the known art, patentability should not be denied merely on the ground that a computer program is involved in its implementation. This means, for example, that program-controlled machines and program-controlled manufacturing and control processes should normally be regarded as patentable subject-matter. It follows also that, where the claimed subject matter is concerned only with the program-controlled internal working of a known computer, the subject-matter could be patentable if it provides a technical effect. As an example consider the case of a known data processing system with a small fast working memory and a larger but slower further memory. Suppose that the two memories are organised under program control, in such a way that a process which needs more address space than the capacity of the fast working memory can be executed at substantially the same speed as if the process data were loaded entirely in that fast memory. The effect of the program in virtually extending the working memory is of a technical character and might therefore support patentability.

Basis: Manual of Substantive Examination Procedure, Chapter IV Article 2.

2. Forms of substances for use in pharmaceutical industry. (see prior discussion above)

B2: Software and Business Method

(1) As to software related inventions, are there any special tests for finding subject matter eligibility?

Yes (**X**) No ()

Reason and/or Basis:

Software related inventions are generally considered as method of doing business inventions. However, if the software program is claimed as a method or system which has a technical effect and it is associated with a technical means, it can be an eligible subject matter for patent protection.

(2) Is the following type of software invention claim allowable?

“A software program”

Yes () No ()

It depends on whether the claimed invention has a technical effect and has a technical means.

(3) Is the following type of software invention claim allowable?

“A computer-readable recording medium which stores a software program”

Yes () No ()

It depends on whether the claimed invention has a technical effect and involves a technical means.

(4) Is the following type of software invention claim allowable?

“A transmission medium (carrier signal) for transferring a software program”

Yes (**X**) No ()

(5) As to software related inventions, is the standard for finding subject matter eligibility different depending on the category of the claim (product claim or process claim)?

Yes () No (**X**)

B3: Biological Inventions

Please answer the following questions regarding biological inventions.

B3-1: Biological Material

Are the following subject matters eligible for a patent?

(1) Nucleic acids (such as genes and vectors):

Yes (**X**) No ()

(Ground/Statutory basis)

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(2) Polypeptides (such as recombinant proteins and antibodies):

Yes (**X**) No ()

(Ground/Statutory basis)

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(3) Animal cells (such as iPS cells):

Yes () No ()

(Ground/Statutory basis)

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(4) Plant cells:

Yes () No ()

(Ground/Statutory basis)

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(5) Microorganisms (such as viruses, bacteria and fungi):

Yes () No ()

(Ground/Statutory basis)

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(6) Plants (including seeds and a part of the plants):

Yes () No ()

(Ground/Statutory basis)

It falls under non-patentable subject matters enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(7) Animals (excluding human):

Yes () No ()

(Ground/Statutory basis)

It falls under non-patentable subject matters enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

B3-2 (Category of subject matter) (Note: this question is only applicable to Groups of a country or region where the above subject matters are not eligible for patents)

Even if any one of the above subject matters by itself is not eligible for a patent, will such subject matter become eligible for a patent if the category of the subject matter is changed into a different category (for example, a production process)?

Yes () No (**X**)

If the answer is “Yes,” is there any ground for supporting your answer or is there any statutory basis (such as a patent law, a patent rule or Examination Guidelines) for supporting your answer?

B3-3 (Others)

Is a genetically modified human or a process for modifying a human gene excluded from a patent eligibility?

Yes (**X**) No ()

(Ground/Statutory basis)

Rule 202 (i) of IRR states “Anything which is contrary to public order, health, welfare, or morality, or process for cloning or modifying the germ line genetic identity of humans or animals or uses of the human embryo.

B4: Medical-related invention

Please answer the following questions regarding medical-related inventions.

When answering the questions, please mention the reason or basis for the answer.

B4-1 (Subject Matter)

Are inventions concerning the following objects patentable?

(1) Method of surgery, therapy, or diagnosis for the human body

Yes () No (**X**)

Reason and/or Basis:

It falls under non-patentable subject matters enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

It is has no industrial applicability.

(2) Method of surgery, therapy, or diagnosisfor non-human animals

Yes () No (**X**)

Reason and/or Basis:

It falls under non-patentable subject matters enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

It is has no industrial applicability.

(3) Medical equipment (e.g., X-ray imaging machine, MRI machine, CT scan machine, system, or program thereof, etc.)

Yes (**X**) No ()

Reason and/or Basis:

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(4) Method of using or operating medical equipment

Yes () No (**X**)

Reason and/or Basis:

It has no technical character or effect and is not industrially applicable.

(5) Medicine

Yes (**X**) No ()

Reason and/or Basis:

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(6) Method of therapy by dosing medicine

Yes () No (**X**)

Reason and/or Basis:

It falls under non-patentable subject matters enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

It is has no industrial applicability.

(7) Alternative organ such as an artificial organ or artificial arm

Yes (**X**) No ()

Reason and/or Basis:

It is considered as a product invention under Section 21 of R.A. 8293 and Rule 201 of IRR.

It does not fall under non-patentable subject matters per se as enumerated in Section 22 of R.A. 8293 and Rule 202 of the IRR.

(8) Methods of implanting a substitute organ such as an artificial internal organs or artificial arm in a human body

Yes () No (**X**)

Reason and/or Basis:

Section 22.3 of R.A. 8293 and Rule 202(f) of IRR states “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods”

B4-2 (Claim Category)

With respect to the medical-related invention, if claim of product is not patentable, is there any possibility of it being patentable by rewriting the claim as the invention of method?

Reversely, if the claim of method is not patentable, is there any possibility of it being patentable by rewriting the claim as the invention of product?
(For example, medical equipment and method of operation of the medical equipment, medicine and method of therapy by dosing the medicine, or medicine defining dose amount and method of therapy by dosing the medicine, etc.)

Yes () No (**X**)

If "Yes", please explain the difference and the reason thereof.

B4-3 (Others)

Are the following inventions patentable?

(1) Cosmetic procedure involving surgery whose purpose is not therapy.

Yes () No (**X**)

Reason and/or Basis:

Section 22.3 of R.A. 8293 and Rule 202(f) of IRR states “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods”

(2) Cosmetic procedure which does not involve surgery whose purpose is not therapy.

Yes (**X**) No ()

Reason and/or Basis:

It does not fall under Section 22.3 of R.A. 8293 and Rule 202(f) of IRR states “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. xxx”

(3) Method of processing sample extracted from a human body

Yes (**X**) No ()

Reason and/or Basis:

The method is done outside the human body; thus it does not fall under Section 22.3 of R.A. 8293 and Rule 202(f) of IRR.

B5: Plant Varieties

Is the protection of plant varieties provided by patent law?

Yes () No (**X**)

C: History of Changing Patent Eligibility

C1 Are inventions listed below now patentable under circumstances in your country?

C2 If “Yes,” and if it has changed from “No” to “Yes” at a certain point of time, please describe when and why it has changed (possible reasons may include: political matters, public interest, request from international treaty, etc.).

List

- (1) Foods and Beverages, or Preferences such as cigarette, etc.
- (2) Medicine and Method for preparing medicine
- (3) Chemical substance
- (4) Nuclear transmutation substance
- (5) Computer program

(1) Yes (**X**) No ()

When:

Why:

(2) Yes (**X**) No ()

When:

Why:

(3) Yes (**X**) No ()

When:

Why:

(4) Yes () No () **NONE**

When:

Why:

(5) Yes () No ()

It depends on whether it has a technical effect and is associated with a technical means.

(See explanation in B1 above)

When:

Why: