

**EXAMINATION GUIDELINES FOR PHARMACEUTICAL PATENT APPLICATIONS
INVOLVING KNOWN SUBSTANCES**

1. INTRODUCTION

This Examination Guidelines provide the methodology to be observed by BOP patent examiners in the examination of applications for patents on drugs and medicines, pursuant to the amendments to the Intellectual Property Code brought by Republic Act 9502 (Universally Accessible Cheaper and Quality Medicines Act of 2008) and its Implementing Rules and Regulations (Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01).

The Examination Guidelines focuses on what ought to be considered in the examination of patent applications for drugs and medicines involving the following:

- 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.

Because of public health considerations, applications involving drugs or medicines involving known substances are granted letters patent only when they satisfy the eligibility standard requiring that the subject matter must not fall in any of the enumeration of non-patentable inventions while meeting the criteria of novelty, inventive step and industrial applicability. Thus, an invention must pass all criteria, and knowledge that is or has become part of public domain, whether explicit or inherent, should not be allowed to crawl back into the patent space.

Recognizing that identical provisions are contained in the sections on non-patentable subject matter and inventive step, the Examination Guidelines provide an explanation on the coherent manner of assessing the patent application against the patent eligibility standard and the patentability criterion of inventive step, consistent with generally accepted principles and practices in patent examination. As demonstrated in the examples, the Examination Guidelines adopts the doctrine of inherency in its expanded sense in order to articulate on the meaning of “mere discovery.” Subjecting the term “mere discovery” to inherency analysis clarifies any ambiguity and provides a more definitive methodology for examiners.

Actual cases decided in the other jurisdictions have been cited in the Examination Guidelines to illustrate the application of the principles used to interpret the relevant QUAMA provisions. However, the same is merely

	<p>explanatory and to be used as reference consistent with the general policy rationale in RA 8293 that an effective intellectual and industrial property system is vital to the development of domestic and creative activity, and with the principle in RA 9502 that places emphasis on the non-eligibility of mere discoveries. Each application must be examined independently and with in-depth analysis of the above considerations.</p>
	<p>2. DEFINITION OF TERMS</p> <p>a. “Drugs and medicines” refer to any chemical compound or biological substance, other than food, intended for use in the alleviation of symptoms and the treatment, prevention or diagnoses of diseases in humans or animals, including but not limited to:</p> <ol style="list-style-type: none"> (1) Articles recognized in the current official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, official Philippine National Drug Formulary (PNDF), British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them; (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; (3) Articles other than food intended to affect the structure or any function of the human body or animals; (4) Articles intended for use as a component of articles specified in clauses (1), (2), or (3) not including devices or their components, parts, or accessories; and (5) Herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine that are: <ol style="list-style-type: none"> (i) Recognized in the Philippine National Drug Formulary Vol. I (Essential Drugs List); (ii) Intended for use in the treatment, cure or mitigation of disease symptoms, injury or body defects in humans; (iii) Other than food, intended to affect the structure or any function of the human body; (iv) In finished or ready-to-use dosage form; and (v) Intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv). (6) In case of conflicts, the BFAD drug classification will prevail. <p>b. “Known substance” refers to known compound or composition wherever applicable.</p> <p>c. “New form” refers to salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes,</p>

	<p>combinations, and other derivatives of a known substance.</p> <p>e. “New use” refers to second or further medical use of a known compound or composition.</p> <p>f. “Process” refers to the preparation/method of manufacture/method of producing a product or composition in view of QUAMA provisions under Section 22.1 of the IP Code, as amended.</p> <p>g. “QUAMA” refers to RA 9502(Universally Accessible Cheaper and Quality Medicines Act of 2008).</p>
<p>Section 22.1 IP Code as amended Rule 8, Section 1, IRR of RA 9502</p> <p>Section 26 IP Code as amended Rule 8 Section 1, IRR of RA 9502</p>	<p>3. GENERAL GUIDELINES</p> <p>The pertinent QUAMA provisions are found in Section 22.1 and Section 26, of the IP Code, as amended.</p> <p>Section 22 of the IP Code, as amended, enumerates the following subject matters excluded from patent protection:</p> <p>22.1 Discoveries, scientific theories and mathematical methods; and 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.</p> <p>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;</p> <p>22.2 xxx; 22.3 xxx; 22.4 xxx; 22.5 xxx; 22.6 xxx;</p> <p>Section 26 of the IP Code, as amended, states that:</p> <p>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.</p> <p>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,</p>

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.

4. MERE DISCOVERY OF NEW FORMS

Section 22 .1 of the IP Code, as amended by the QUAMA enumerates those excluded from patent protection, to wit:

“22.1 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.”

A pharmaceutical compound comes in various new forms, such as salts, amorphous form; polymorphs; isomers; metabolites; pure form; new particle size; combination with other pharmaceutical substances; ester, ether or other derivatives.

4.1 NON-PATENTABLE SUBJECT MATTER INQUIRY

A claimed new form of a known compound maybe objected as non-patentable subject matter if it falls within the context of the inherency principles as itemized in 4.1.1 to 4.1.3.

4.1.1 “In general, a limitation or the entire invention is inherent and in the public domain if it is the “natural result flowing from” the explicit disclosure of the prior art.”

4.1.2 “To establish inherency, a person of ordinary skill in the art is not required to recognize the inherent disclosure in the prior art.”

ILLUSTRATIVE EXAMPLES:

Example 1:

INVENTION: Metabolite B of compound A as a non-drowsy antihistamine.

PRIOR ART: A class of compounds called antihistamines, including compound A. The administration of compound A to a patient is also taught. However, said reference does not expressly disclose metabolites of compound A and does not refer to any compound that is identifiable as metabolite B.

A patient ingesting compound A would necessarily metabolize that compound to metabolite B. Hence, metabolite B is considered as inherent even though its existence was not known at the time the prior art is created because it is the “natural result flowing from” the explicit disclosure of administering the compound A to a patient.

It is not required that a skilled artisan has to recognize the inherent characteristic in the prior art to establish inherency when (a) metabolite B is a necessary consequence of administering compound A to patients i.e. is not formed accidentally or under unusual conditions when compound A is ingested and (b) necessarily and inevitably forms from compound A under normal conditions.

Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the “natural result flowing from” the explicit disclosure of the prior art.

With proper claiming, patent protection is available for metabolites of known drugs. The metabolite maybe claimed in its pure form and isolated form or as a pharmaceutical composition.

Example 2:

INVENTION: Hemihydrate form of compound C.

PRIOR ART: Method of manufacturing the anhydrous form of compound C that naturally results in the production of at least trace amounts of the hemihydrate form

The claim directed to the hemihydrate form of compound C is inherently disclosed by the prior art relating to the production of the anhydrous form because a small fraction of the anhydrous form spontaneously converted to the hemihydrate form. Since the claims covered compounds that were the natural and necessary result of prior art process, notwithstanding that the art may not have recognized or appreciated the compounds, the claims are inherently disclosed.

The hemihydrate form of compound C is held inherent when (a) producing the anhydrous form according to the prior art’s process inevitably results in the production of at least trace amounts of the hemihydrate form, (b) it was undisputed that the first known existence of the hemihydrate form resulted from an attempt to produce the anhydrous form according to the prior art.

4.1.3 “Inventor’s discovery of scientific principles does not entitle him to remove prior art from public domain.”

Example 3:

INVENTION: Composition of a vitamin supplement that is “essentially free of antioxidants”.

PRIOR ART: Several vitamin supplements. The addition of other antioxidants in combination with these vitamin supplements is also taught to provide synergistic health benefits. Thus, the optional supplementation of its vitamins with these antioxidants is disclosed.

The inventor of the claimed vitamin supplement discovered that the supplemental antioxidants would actually destroy some of the vitamins. Based on this finding, the inventor distinguished the prior art by expressly excluding the supplemental antioxidants.

The only difference between the claimed invention and the prior art was the negative limitation expressly excluding the antioxidants. The prior art's "optional inclusion" of antioxidants teaches vitamin supplement compositions that both do and do not contain antioxidants. Hence, despite no express teaching to exclude the antioxidants in the prior art, the claimed vitamin composition is inherently disclosed because the composition without antioxidants was already enabled.

The discovery of the scientific principles explaining the reasons that prior art vitamin supplement compositions essentially free of antioxidants are more effective than similar compositions containing antioxidants does not entitle the inventor to remove that prior art from the public domain by patenting those compositions.

One cannot withdraw some vitamin compositions from the public domain by explaining or purporting to claim the scientific underpinnings of their operation.

4.2 ENHANCED EFFICACY (Inventive Step)

The enhancement of known efficacy will only be considered during assessment on the inventive step of the claimed new form of the known substance. Hence, where enhancement of the known efficacy arises, it implies an inventive step issue within the purview of the QUAMA provision.

In this guideline, the expanded definition of efficacy is adopted. Efficacy may refer to the "therapeutic efficacy" or to any of the "advantageous properties" (e.g. bioavailability, stability, solubility among others) exhibited by the new form of a known substance. Consequently, enhancement of efficacy may also refer to the improved or unexpected properties of known pharmaceutical substances such as increased bioavailability, lower neurotoxicity, higher potency, which are not found in the original pharmaceutical substance.

Enhanced efficacy can also be proved by factors such as lesser side-effects, wider spectrum of activity, reduction in treatment time etc.

"From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, and the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared...the thing that is patented is not the formula but the compound identified by it...There is no basis in law for ignoring any property in making such a comparison."

Efficacy requires that applicants demonstrate that the new form of a known substance exhibits an "unexpected" or "improved" result that is not restricted solely in its "therapeutic" advantages, which would then provide for the enhancement of the known efficacy.

Efficacy need not be quantified in terms of numerical value to determine whether a product is efficacious because it is not possible to have a standard numerical value for efficacy for all pharmaceutical products.

For purposes of establishing that a new form or a new property differs significantly with regard to efficacy as compared with the known substance, a patent applicant must provide data comparing the efficacy of the new form with that of a known substance.

A reasonable correlation between the efficacy claimed and the data provided shall be demonstrated and substantiated by relevant data documenting the activity of the new form, relevant results of experimental assays (*in vivo* and/or *in vitro*), other pre-clinical or clinical test data, or any combination thereof.

Due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such science that the new form of a known substance had resulted in the enhancement of the known efficacy of the original substance.

The reference point for any comparison with regard to properties or enhancement of efficacy should be the filing date of the application or the relevant priority date, if the application is claiming the priority of any earlier application, but not at the stage of subsequent development. This is because a patent is granted on the basis of its full disclosure of the invention in the description furnished on the priority date of the application.

When assessing the extent of enhancement of efficacy, the patent examiner may call on representatives of the Food and Drug Administration (FDA), formerly the Bureau of Food and Drugs (BFAD), and/or its delegated experts to provide an expert opinion with regard to significant enhancement of therapeutic efficacy. Such expert opinion, however, is not binding but serves only as guide in the determination of inventive step in relation to the efficacy of a drug or medicine.

Rule 8, Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01 (IRR of R.A. 9502)

4.2.1 “Patentability is not imparted where the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success.”

ILLUSTRATIVE EXAMPLE:

INVENTION: A besylate form of a known compound A that has unexpected superiority in terms of combination of properties vis-à-vis its maleate form, i.e. possesses a highly desirable combination of physicochemical properties including good solubility, stability, non-hygroscopicity, and processability necessary for producing a commercial product.

*PRIOR ART 1: Genus of pharmaceutically acceptable salts of compound A;
PRIOR ART 2: Commercially marketed anions, including benzene sulphonate useful for making pharmaceutically-acceptable salts;
PRIOR ART 3: Benzene sulphonic acids that considerably increase the solubility of*

pharmaceuticals;

PRIOR ART 4: Besylate as the preferred pharmaceutically-acceptable acid addition salt form of a pharmaceutical compound;

PRIOR ART 5: An intermediate dihydropyridine compound useful in the form of an acid addition salt derived from benzene sulphonate; and

PRIOR ART 6: A besylate acid addition salt form of a pharmaceutical composition having excellent pharmacokinetic properties, near-optimal solubility, and improved stability.

The besylate form of compound A is considered as lacking inventive step when there is motivation to make the besylate form of compound A from the combined prior art references, resulting from the “nature of the problems” (chemical instability and stickiness problems) encountered with the manufacture of the maleate form tablet formulations of compound A, in order to achieve the claimed invention.

Benzene sulphonate would have been favored by a skilled artisan because of its known acid strength, solubility, and other known chemical characteristics as disclosed in the prior art references; likewise, a skilled artisan would have engaged in routine verification testing to optimize selection of one of the several known and clearly suggested pharmaceutically acceptable salts of compound A to ease the manufacture of the tablet formulations of compound A.

A rule of law equating unpredictability to patentability, applied in this case, would mean that any new salt would be separately patentable, simply because the formation and properties of each salt must be verified through testing. This cannot be the proper standard since the expectation of success need only be reasonable, not absolute.

4.2.2 “Disclosure of Racemate Does Not Render *d*-enantiomers and *l*-enantiomers Obvious, Especially in Light of Unexpected Results”

ILLUSTRATIVE EXAMPLES:

Example 1:

INVENTION: A substantially pure (+)-enantiomer of compound A and non-toxic acid addition salts thereof, which is a selective serotonin reuptake inhibitor (SSRI) used in the treatment of depression.

PRIOR ART: A racemic mixture of compound A and descriptions of techniques available to separate enantiomers from their racemates.

The substantially pure (+)-enantiomer of compound A is considered to involve inventive step when the known difficulty of separating enantiomers and the unpredictability of their properties are not disclosed in the prior art, i.e. any prima facie obviousness based on racemic form of the compound A is rebutted by the evidence demonstrating the difficulty of separating the enantiomers and the unexpected properties of the (+)-enantiomer of compound A.

Further, in light of the unexpected result that all of the therapeutic benefit of the compound A would reside in its (+)-enantiomer resulting in having twice the potency of the racemic compound, it would not have been obvious in view of the known racemate, when *it was shown that the therapeutic properties of the (+)-enantiomer were unexpected.*

Lastly, that the prior art would not have provided the skilled person with a reasonable expectation of success at separating the enantiomers of the compound A when the difficulty involved in the separation would have motivated the skilled person to develop new compounds.

Example 2:

INVENTION: A bisulfate salt of the d-enantiomer of compound A substantially separated from the l-enantiomer, which has the property of inhibiting the aggregation of blood platelets, and is used to treat or prevent blood-thrombotic events such as heart attacks and strokes.

PRIOR ART: A class of thienopyridines that disclosed examples of its specific compounds including the racemic form of compound A.

The bisulfate salt of the *d*-enantiomer of compound A is considered to involve inventive step when the *unpredictable and unusual properties of the d-enantiomer of compound A and its therapeutic advantages* resulting from the absolute stereospecificity of the *d*-enantiomer are not disclosed in the prior art, i.e. an unexpected and rare finding that the *d*-enantiomer of compound A exhibited all of the biological activity (or anti-platelet activity) while its *l*-enantiomer exhibited all those concerning neurotoxicity.

In light of the unexpected result exhibited by the *d*-enantiomer of compound A, it can be said that for “chemical compounds, the structure of the compound and its properties are inseparable considerations in the obviousness determination”, which in this case, a skilled artisan would not have had the expectation that the separation of enantiomers would be likely to produce an isomer having absolute stereospecificity as to both the favorable antiplatelet activity and the unfavorable neurotoxicity and that the separation was not a simple or routine procedure and that success in the separation, as well as the allocation of properties, was unpredictable.

Example 3:

INVENTION: The l-isomer of compound A that is twice as potent, about ten times more soluble, and appreciably less toxic; the drug also has better pharmacokinetics and lower levels of bacterial resistance.

PRIOR ART: The racemic form of compound A.

The *l*-isomer of compound A is considered to involve inventive step when the improvement involving an increased solubility is substantial and that the combination of the properties are unexpected over its racemic form, i.e. the *l*-isomer of compound A was twice as active, about ten times more soluble at neutral pH, and less toxic than its racemate. Thus, is pharmaceutically

superior in virtually every relevant aspect.

Enantiomers are not prima facie obvious in light of their racemates, if by clear and convincing evidence a person of ordinary skill in the art would not have had a reasonable expectation of success in producing the *L*-isomer of compound A.

4.2.3 “When a new compound so closely related to a prior art compound as to be structurally obvious is sought to be patented *based on the alleged greater effectiveness of the new compound for the same purpose as the old compound, clear and convincing evidence of substantially greater effectiveness is needed.*”

ILLUSTRATIVE EXAMPLE:

INVENTION: A piperidinol ester, an analgesic, with an increased level of activity that is approximately a nineteen-fold increase.

PRIOR ART: A “reverse ester” compound derived from piperidine carboxylic acids.

The piperidinol ester is considered to involve inventive step when the prior art makes no suggestion that a reversal of the ester linkage would result in an increased activity, approximately the nineteen-fold increase.

At the very best, the prior art suggests an increase of the order of four to eight times. The question is not whether an improvement is suggested, but rather whether the particular improvement is reasonably suggested, relied upon for patentability in both its qualitative and quantitative sense.

4.2.4 “The recognition of a need does not render obvious the achievement that meets that need; recognition of an unsolved problem does not render the solution obvious.”

ILLUSTRATIVE EXAMPLE:

INVENTION: An extended release pharmaceutical composition comprising compound B (a derivative of the known compound A) and a pharmaceutically acceptable polymer, for reducing gastrointestinal side-effects, whereby after ingestion certain specified parameters (pK limitations) of drug bioavailability are met.

PRIOR ART 1: Extended release formulations of compound A;

PRIOR ART 2: Extended release formulations of compound C (another derivative of the known compound A) and their pK profiles; and

PRIOR ART 3: Extended release of a drug including compound B as an alginate salt.

An extended release formulation of the antibiotic drug compound B, which aims to extend the period of drug effectiveness after ingestion and thereby

reduce the requisite frequency of dosage, is considered to involve inventive step when the claimed pK limitations were not disclosed in any of the prior art as well as that there was no motivation for a skilled person to combine the teachings of the prior art references and come up with a reasonable expectation of success, i.e. a skilled artisan would not have predicted which formulation, selected from the prior art, would provide the required pharmacokinetics, and when there are dissimilarities in the pharmacokinetic properties and that the bioavailability of the formulations in the invention are not predictable from the prior art.

When the problem is known, the possible approaches to solving the problem are known and finite, and the solution is predictable through use of a known option, then the pursuit of the known option may be obvious even absent a “teaching, suggestion, or motivation” concerning that option. If this leads to the anticipated success, it is the product of ordinary skill and common sense and not of innovation.

4.2.5 “If the synergy demonstrated by the new combination is no greater than the equivalent prior art combination, then it does not provide evidence of inventive step.”

An admixture resulting into unexpected results or synergistic properties of a mixture is considered as exhibiting enhanced efficacy. The existence of synergy requires that the relationship between the features or groups of features be one of functional reciprocity or that they show a combinative effect beyond the sum of their individual effects. The features should be functionally linked together which is characteristic of a combination invention.

If a synergistic effect is to be relied on as a manifestation of inventive step, it must be appropriately described and proven in the patent specification (for instance, on the basis of biological tests, bioavailability, stability tests, etc).

ILLUSTRATIVE EXAMPLES (Synergistic Effect):

Example 1:

INVENTION: A pharmaceutical composition for treating inflammatory diseases, comprising (a) an effective amount of compound A or its salts, and (b) an effective amount of a nonsteroidal anti-inflammatory agent other than compound A or its salt, for instance, compound B. The phrase "in a quantity producing a synergistic effect" is inserted between "nonsteroidal anti-inflammatory agent" and "the anti-inflammatory agent being".

PRIOR ART: A pharmaceutical composition for treating inflammatory diseases, comprising (a) an effective amount of compound A or its salt; and, (b) an effective amount of a nonsteroidal anti-inflammatory agent being for instance compound C.

The anti-inflammatory pharmaceutical composition of the invention is considered as lacking inventive step when the inhibitory rate of the combination of the prior art (compound C/compound A) is still higher than the rate of the invention (compound B/compound A) - 52.0% versus 46.3%; both combinations again being equally classified as showing a "very great

synergistic effect".

Thus, there is no advantage of the combined anti-inflammatory agent claimed in the main request over the prior art that could serve to define a special problem that would have been solved by inventive activity.

Example 2:

INVENTION: Combination of compound A and compound B that is superior in terms of potency and spectrum. Compound A, which is a broad antibacterial spectrum of quinolones, has very high gram-negative activity, including moderate activity against Pseudomonas aeruginosa; in combination with compound B, a nitroimidazole which has an antibacterial spectrum that includes most of anaerobes.

PRIOR ART: Monotherapy with both ofloxacin and ornidazole caused mild to moderate hepatotoxicity and nephrotoxicity.

A fixed dose combination of compound A and compound B is considered to involve inventive step since it showed antioxidant potential and offers no obvious toxicity as compared to individual drug treatment. Also, the additive advantage over monotherapy is that both drugs act on DNA and provide sequential block on bacterial DNA to contribute to synergistic activity.

5. MERE DISCOVERY OF NEW USE

Section 22 .1 of the IP Code, as amended by the QUAMA enumerates those excluded from patent protection, to wit:

“22.1 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.”

“New use” as used in the QUAMA provision would refer to second or further medical uses of known compounds.

With the effectivity of the QUAMA, second medical use of known substances or compositions may be covered by patent protection if it satisfies the eligibility standard requirement on “mere discoveries”, i.e. inherency. Likewise, any application for patent protection shall pass the three (3) criteria of patentability of novelty, inventive step and industrial applicability; where the novelty is derived from the claimed new use.

Second (further) medical use claims should be drafted as Swiss-Type claims as discussed in Part 9 of this Guidelines. The examiner should be vigilant that a method of treatment drafted as a second medical use claim format shall not be allowed in view of Section 22.3 of the IP Code.

For a medical application to be construed as a “further medical use” which is not inherent in the prior art, the new technical effect would have led to a truly new therapeutic application, such as the healing of a different pathology or the treatment of the same disease with the same compound, however, when carried out on a new group of subjects distinguishable from the previously suggested subjects for such treatment or would have led to new dosage forms of the known composition.

A second (further) medical use which is not inherent in the prior art would not necessarily mean that it is also inventive. The problem-solution approach will still be applied during the assessment of inventive step focusing on the claimed specified new use vis-a-vis any prior use in the art.

5.1 NON-PATENTABLE SUBJECT MATTER INQUIRY

A claimed new use for a known substance maybe objected as non patentable subject matter if it all falls within the context of the inherency principles as itemized in 5.1.1-5.1.4.

5.1.1 “The mere explanation of an effect obtained when using a compound in a known composition, even if the effect was not known to be due to this compound in the known composition, is inherently disclosed on a known process if the skilled person was aware of the occurrence of the desired effect.”

ILLUSTRATIVE EXAMPLE:

INVENTION: Use of a retinoid compound in a compulsory association with the simultaneous, separate or sequential use of corticosteroids in the prevention of skin atrophy.

PRIOR ART: Combined use of a corticosteroid and a retinoid. It is also recognized that skin atrophy induced by corticosteroids is accompanied by strong symptoms that cannot be overlooked. The prior art did not explicitly disclose that the symptom of skin atrophy caused by the topical application of corticosteroids could be prevented or reduced by the topical use of retinoid.

In this particular case, the claim relates to the mere explanation of the effect obtained when using retinoid in the known composition, the explanation relating to the prevention of skin atrophy which was not known to be due to the retinoid. The claim is considered to be inherent—because the skilled person was already aware of the occurrence of the desired effect of the retinoid when using the known composition.

5.1.2 “A newly discovered technical effect or mechanism of action is inherent if it already underlies the known use of the known substance”

ILLUSTRATIVE EXAMPLES:

Example 1

INVENTION: Use of a compound X for the manufacture of a medicament for the treatment of diseases mediated by the 5-HT_a receptor

PRIOR ART: Compound X useful for the treatment of anxiety.

Given a prior art that discloses compound X for the treatment of anxiety, the applicant claims a mechanism of action for compound X, which is considered merely to represent more information about the known use, i.e. the explanation of the mechanism of action underlying the previous use, without ending up in a new purpose reflecting the said effect.

The second medical indication is inherent in the prior art, hence not a patentable subject matter.

Example 2

INVENTION: The use of Insulin-like growth factor (IGF-1) and/or a biologically active analogue of IGF-1 in the manufacture of a medicament for use in reducing the loss of glial cells or non- cholinergic neuronal cells suffered after a CNS insult.

PRIOR ART: The use of IGF-1 in the preparation of a medicament for use in the treatment of a CNS insult has already been proposed i.e. an application of IGF-1 in the treatment of Parkinson's disease. Prior art is rather concerned with the more general teaching that IGF-1 can heal a CNS disease by "enhancing the survival of neuronal cells".

The mechanism of action underlying the therapeutic effect of IGF-1 is, inter alia, the rescue by IGF-1 of neuronal cells, preferably non-mitotic neuronal cells and/or cholinergic neuronal cells.

The claimed invention can only be regarded as the discovery of additional items of knowledge about further mechanisms of action underlying the known therapeutic application of IGF-1 in the treatment of CNS insults, hence considered as inherent from the prior art.

The claim related to the medical use of IGF-1 in the treatment of a CNS insult, as the wording "reducing the loss of glial cells or non- cholinergic neuronal cells" which is the mere explanation of the mechanism of action of IGF-1, is not a patentable subject matter under QUAMA provision.

5.1.3 "A representative disease falling within the known working mechanism thereof is considered as inherent"

ILLUSTRATIVE EXAMPLES

INVENTION: Compound A as anti-pulmonary asthma

PRIOR ART: Compound A as bronchodilator

INVENTION: Compound B as hypotensive agent

PRIOR ART: Compound B as vasodilator

INVENTION: Compound C as therapeutic agent for angina

PRIOR ART: Compound C as coronary vessel dilator

INVENTION: Compound D as anti-allergy

PRIOR ART: Compound D as histamine liberation inhibitor

INVENTION: Compound E as agent for gastric ulcer

PRIOR ART: Compound E as histamine H-2 receptor inhibitor

5.2 INVENTIVE STEP

Where the agent has been used to treat a related condition, then inventive step of the the claim should be assessed carefully taking into account the merits of each application. If the diseases have a common origin, causative factors or mechanism, the claim may lack inventive step.

In relation to cancer treatments, there are no “magic bullets” which successfully treat all cancers because different types of cancers have different causes and characteristics. The disclosure that a particular treatment is effective against one or more cancer types would not normally indicate a “reasonable expectation of success” in the treatment of an unrelated form of cancer.

The examiner may refer to the following illustrative cases during inventive step assessment of second(further) medical uses of known substances.

5.2.1 “If the manifestations of the second more serious disease are known to run through the manifestations of the first disease, and this assumption reliably substantiated was not confuted, then the activity of a medicament against the more serious disease would already strongly suggest an effect also against the less serious one.”

ILLUSTRATIVE EXAMPLE:

INVENTION: The use of prenyl ketone compound of formula (I) ...for the preparation of a medicament for the treatment or prophylaxis of inflammation of the gastric mucosa

PRIOR ART 1: The anti-ulcer effect of the prenyl ketone of the claim, i.e. geranylgeranylacetone (GGA), on experimentally induced gastric and duodenal ulcers in rats was disclosed.

PRIOR ART 2: The protecting effect of GGA against ulcer and to its protection against gastric mucosal damage in general induced by acetylsalicylic acid was also known. It was also disclosed that gastritis and ulcer are considered as distinct diseases characterized by different pathology.

The technical problem to be solved in relation to the prior art is to extend the field of therapeutic application of the prenyl ketone and that the solution proposed by the application is the use for the preparation of a medicament

for the treatment of gastritis.

It is known that certain drugs such as aspirin and other non-steroidal anti-inflammatory drugs predispose to formation of an ulcer. It is also known that aspirin or other anti-inflammatory agents can generate gastritis.

Though gastritis and ulcer are distinct diseases, they have common aspects in relation to their “causative factors”. Thus, the skilled person would expect that the cytoprotective activity of GGA applies to any kind attack by a mucous breaker aggressive agent such as acetylsalicylic acid, regardless of whether it eventually leads to gastritis or ulcer.

5.2.2 “Without the exercise of any inventive ingenuity, any additional advantage, even if unexpected, could only be considered as a gratis effect which would inevitably have resulted from the non-inventive activity.”

ILLUSTRATIVE EXAMPLE:

INVENTION: Second medical use of the Compound A directed to the treatment of erectile dysfunction in a male animal. Compound A is a potent and selective inhibitors of guanosine 3,5-monophosphate PDE's, more specifically phosphodiesterase (PDE)v.

PRIOR ART 1: Compound B as a cGMP PDE inhibitor, which enhances the relaxation of the muscle responsible for causing an erection

PRIOR ART 2: Compound B as PDE_v inhibitor, which causes relaxation in strips of human corpus cavernosum. Therapeutic activities could include treatment of impotence. It is also known in the art that compound B is a weak and non-selective PDE_v inhibitor.

There is a clear disclosure in the prior art: (i) that use of PDE_v inhibitors elevate cGMP; (ii) that smooth muscle relaxation appears to be the most promising of the potential uses of PDE_v inhibitors; (iii) possible uses of PDE_v include, amongst others, the treatment of impotence; (iv) a clearer picture will be obtained when other rationally designed inhibitors become available.

The prior art explicitly provided the way forward. PDE_v inhibitors were said to be potentially useful for the treatment of MED and that a clearer picture would be obtained when inhibitors, other than the three mentioned, became available. Hence, the invention is obvious from the disclosure of the prior art.

Without the exercise of any inventive ingenuity, any additional advantage, even if unexpected, could only be considered as a gratis effect which would inevitably have resulted from the non-inventive activity. There could be no invention in doing what was suggested.

6. MERE USE OF KNOWN PROCESS

Section 22 .1 of the IP Code, as amended by the QUAMA enumerates those excluded from patent protection, to wit:

“22.1 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.”

6.1 NON-PATENTABLE SUBJECT MATTER INQUIRY

A claimed process may be objected as non-patentable subject matter if it falls within the context of the inherency principles as itemized below:

6.1.1 “A prior art reference without express reference to a claim limitation may nonetheless disclose by inherency.”

6.1.2 “Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.”

6.1.3 “Newly discovered results of known processes are not patentable because those results are inherent in the known processes.”

6.1.4 “The recognition of a new aspect of a known process is not a patentable invention of a novel process.”

ILLUSTRATIVE EXAMPLE:

INVENTION: A process for preparing an oral formulation of Compound A directed at the formation of a water-soluble separating layer between the acid-sensitive core and the enteric coating, wherein the separating layer was formed in situ by a reaction between the ingredients in the core and in the enteric coating. The claimed process produces a Compound A formulation with three distinct layers, but starts with only two of the three layers.

PRIOR ART: A two-step process of preparing an oral pharmaceutical formulation including core ingredients such as Compound A and enteric coating ingredients, with no enteric coating process conditions. The enteric coating process conditions were maintained as a Trade Secret.

Though the inventors may not have recognized that a characteristic of prior art's process ingredients resulted in an *in situ* formation of a separating layer, the *in situ* formation is inherent when it was a natural result flowing from the combination of certain ingredients listed in the prior art's process, i.e. the combination of ingredients in the core and enteric coating ingredients

	<p>necessarily resulted in <i>in situ</i> formation of a separating layer.</p> <p>To establish inherency, a person of ordinary skill in the art is not required to recognize the inherent disclosure in the prior art. Thus, the absence of any disclosure of the prior art’s process by which the known formulation was made is not significant.</p> <p>6.2 INVENTIVE STEP</p> <p>A claim to a process which is not inherent in the prior art would be a patentable subject matter. However, this does not mean that such process will necessarily be inventive. The problem-solution approach will still apply during assessment on inventive step focusing on the claimed process vis-à-vis any prior process disclosed in the art.</p>
	<p>7. CLAIMING MEDICAL INDICATION</p> <p>When the Philippines adopted the First to File System, the IP Code under Republic Act 8293 was crafted based on European Patent Convention (EPC) 1973. Under RA 8293, Section 22.3 of the IP Code excludes methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. The policy behind the exclusion of such methods was clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents.</p> <p>Methods of treatment not falling within the scope of the terms “therapy” and “surgery” are not excluded from patentability. Furthermore, claims to methods of diagnosis are objectionable if they are performed directly on the human body or animal body.</p> <p>The provision in Section 22.3 of the IP Code shall not apply to products, in particular, substances or compositions, for use in any of these methods. Thus, a drug that would be used in preventing or treating a medical condition could be patented, while the treatment itself would be unpatentable.</p> <p>An application filed in the Philippines which includes unpatentable method of treatment claims, such as the use of X to treat Y, the amendment of these claims to redraft them into second medical use claim format does not constitute added matter and thus accepted anytime during examination stage. However, the examiner shall exercise vigilance in assessing claims on method of treatment disguised as a second medical use.</p>
	<p>7.1 EVIDENCE OF SUPPORT IN THE DESCRIPTION</p> <p>A claim to the first medical use of a known substance or composition should be supported by evidence of its efficacy in therapy, surgery or diagnosis since the claims are distinguished from the prior art by their use. This requirement is also applicable to second (further) medical use invention.</p> <p>The evidence maybe in the form of clinical test results, experimental results on an animal model, or in vivo or in vitro data. In the absence of any such</p>

	<p>evidence, the claim is considered as merely speculative and a support objection should always be made.</p> <p>If the first or second (further) medical use claim is included as a subsidiary claim to a new and inventive substance or composition, further consideration of support for the medical use claim is not necessary.</p>
	<p>7.2 METHOD OF TREATMENT BY THERAPY</p> <p>“Therapy” is defined as “any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the animal body”. Veterinary treatment of a sick or injured animal is also regarded as therapy.</p> <p>The following drafts of claims are construed to define methods of treatment by therapy, and are thus excluded from patent protection in view of Section 22.3 of the IP Code:</p> <ul style="list-style-type: none"> i) Method of treating disease Y by administering (a therapeutically effective amount of) a substance or composition X ii) The treatment of disease Y with substance X iii) The use of substance X to treat medical condition Y iv) Substance X when used to treat medical condition Y v) The use of substance X as a pharmaceutical vi) Use of a substance or composition X as a medicament for the treatment of disease Y <p>A claim to the use of a substance “as a pharmaceutical” or “as a medicament” is interpreted as a method claim to the use of the substance in therapeutic treatment, rather than simply a claim to its use in a pharmaceutical formulation.</p>
	<p>7.2.1 Determining “Treatment by Therapy”</p> <p>Section 22.3 has an intention of ensuring that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents, thus, a claimed method which does not have an impact on a medical practitioner’s discretion is likely to fall outside the scope of Section 22.3.</p> <p>As such, a method in which a laser was used to modify a synthetic lenticule implanted on the cornea would be considered as method of treatment in part because it would be performed by or under the supervision of a medical practitioner.</p>
	<p>7.2.2 Therapeutic and Non-Therapeutic Methods: Specific Examples</p> <p>The following specific examples will clarify what methods of treatment falls within the definition of “therapy”.</p> <p>i. Cosmetic Treatments</p> <p>Purely cosmetic treatments of the skin and hair do not fall under Section 22.3 of the IP Code. These methods may include strengthening hair and</p>

using a composition to protect the lips from sunburn.

Methods of protecting the skin by simply blocking UV radiation are not considered to be therapy, but if the method includes physiological effects then it is considered as “therapy”. Specifically, if the cosmetic and therapeutic aspects of the claimed method of protecting skin are “inevitably linked, such that each one necessarily develops together with the other and such that is impossible to separate them”, the method is therapeutic.

The use of composition for the local treatment of blackheads was purely cosmetic method of non-medical body hygiene, however, it would be therapeutic when it was applied for the treatment of acne.

ii. Removal of Parasites

A method of treating or preventing infestation of internal parasites is considered as therapeutic as well as treatment of parasites residing on the skin of a human or animal. For example, treatment of head lice is a treatment by therapy.

iii. Oral Care

Methods for the removal of dental plaque, or preventing the formation of plaque have the effect of treating or preventing dental caries, thus therapeutic.

iv. Pain, Fatigue and Addiction

The relief of pain is regarded as therapeutic. Irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as “therapy”. On the other hand, reducing fatigue was not comparable with the relief of pain, thus, could be considered as non-therapeutic. Methods to stop smoking, among others as treatment of addiction or withdrawal symptoms are considered as therapeutic methods.

v. Obesity and Weight Reduction

A method in treating obesity is considered as therapeutic. On the other hand, a claim to a “method of improving the bodily appearance of a non-opiate-addicted mammal” relating to cosmetic weight loss only, is considered as patentable subject matter in view of Section 22.3 of the IP Code.

vi. Contraception, Abortion and Fertility Treatment

An application with a claim for a method of contraception, which is to be applied in the private and personal sphere of a human being, is not a patentable subject matter. Also, methods of abortion, termination of pregnancy or induction of labor are regarded as unpatentable treatments regardless of the reasons for performing these methods.

vii. Methods Utilizing Implanted Devices

A method of operating a pacemaker in which its output to the heart is adjusted is regarded as method of treatment. However, a method of controlling the input energy to a pacemaker which does not affect the output to the heart is non-therapeutic. In other words, methods concerning with the operation of a device without functional link between the claimed method and the effects produced by the device on the body is not regarded as

	<p>method of treatment.</p> <p>viii. Treatments Performed Outside the Body A treatment to be excluded would generally have to be carried out on the living human or animal body. A treatment practiced on a dead human or animal body would therefore not be excluded from patentability by virtue of Sec.22.3. Treatment of body tissues or fluids after they have been removed from the human or animal body is not excluded from patentability in so far as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded.</p> <p>ix. Treatment of Stock Animals Sec.22.3 excludes only methods of treatment by therapy, surgery or diagnosis. It follows that other methods of treatment of live human beings or animals (e.g. treatment of an animal in order to improve their meat or milk yields, to promote growth, to improve the quality of mutton or to increase the yield of wool) or other methods of measuring or recording characteristics of the animal body are patentable subject matter. For example, using a medication to increase milk production in cows maybe acceptable if it is shown that the success of the treatment is not a mere consequence of animal’s state of health.</p> <p>x. New Dosage Forms A medical use claim defined by a new dosage form should not be objected to as being an unpatentable method of treatment when the following conditions are met:</p> <ul style="list-style-type: none"> a) The dosage-specific claim is considered to be directed at the manufacturer, distinguished from the claim which defined a series of steps performed by the doctor; b) The new dosage may necessarily result in the use of a wholly different composition, for example, where the active agent is present at a different concentration compared with the prior art. <p>However, this does not mean that such a claim will necessarily be inventive. Thus, inventive step of this type of claim should be carefully scrutinized.</p> <p>xi. New Time, Frequency of Administration A medical use claim defined solely by new time or frequency of administration are construed to be methods of treatment directed at the activity of the doctor, thus not patentable under Section 22.3 of the IP Code.</p>
	<p>7.3 METHOD OF TREATMENT BY SURGERY</p> <p>Surgery is defined as the treatment of the body by operation or manipulation. It is not limited to cutting the body but includes manipulation such as the setting of broken bones or relocating dislocated joints, also referred as “closed surgery”, and also dental surgery.</p> <p>“Treatment by surgery” include those interventions which, whatever their specific purpose, give priority to maintaining the life and health of the human or animal body on which they are performed. As such, the definition</p>

	<p>of surgery includes “endoscopy, puncture, injection, excision and catheterization. However, methods involving relatively low levels of technical expertise (such as simple injection methods for taking blood samples or introducing compositions) would not be regarded as method of surgery. On the other hand, lumbar punctures to deliver epidural injections would fall as method of surgery.</p> <p>Surgery defines the nature of the treatment rather than its purpose. Thus, e.g. a method of treatment by surgery for cosmetic purposes is excluded, as well as surgical treatment for therapeutic purposes or other non-therapeutic purposes such as sterilization.</p> <p>A claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body and which entails a substantial health risk even when carried out with the required professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Section 22.3 of the IP Code.</p>
	<p>7.4 METHOD OF TREATMENT BY DIAGNOSTIC METHODS</p> <p>Diagnostic methods likewise do not cover all methods related to diagnosis. Methods for obtaining information only (data, physical quantities) from the living human or animal body is not necessarily excluded by Sec.22.3, if the information obtained merely provides intermediate results which on their own do not enable a decision to be made on the treatment. Examples of such methods include X-ray investigations, NMR studies, and blood pressure measurements.</p> <p>In order to be excluded from patent protection, a method should fall within the definition of a “method of diagnosis” and whether it is “practiced on the human or animal body”. It is not dependent on who carries out the method. Such method can be practiced by medical practitioner, medicinal or non medicinal support staff, the patient himself or herself or an automated system.</p>
	<p>7.4.1 Defining diagnosis and “practiced on the human or animal body”</p> <p>Diagnosis is defined as the determination of the nature of a medical condition, usually by investigating its history, aetiology and symptoms and by applying tests. It includes a negative finding that a particular condition can be ruled out, as well as a positive identification of a disease.</p> <p>Methods of diagnosis involves a number of steps characterized as follows:</p> <ol style="list-style-type: none"> (1) the examination and collection of data; (2) comparison of the data with normal values; (3) recording any deviation from the norm; and finally (4) attributing the deviation to a particular clinical picture. <p>If a claimed method includes all these steps leading towards identification of a medical condition, it clearly falls within the definition of method of diagnosis. During examination, the examiner should be able to determine if</p>

	<p>the intermediate steps are implied.</p> <p>Moreover, a diagnostic method, to be excluded, would generally have to be carried out on the living human or animal body. A method is excluded if all the technical steps as recited above are practiced on the human or animal body. Therefore, methods of <i>in vitro</i> diagnostic tests, performed on blood or other samples removed from the body, are patentable subject matter. A method carried out on a dead body, for example to determine the cause of death, is also patentable.</p> <p>In most cases, the examination and collection of data (the first step) is the only one that may be “practiced on the body” and considered as the only technical step.</p> <p>“To decide whether a particular step in a method is “practised on the human or animal body”, the key test is whether the step requires the presence of the patient to perform it. It is irrelevant whether the procedure is invasive, or capable of causing harm to the patient.</p>
	<p>7.4.2 Diagnostic and Non-diagnostic Methods: Specific Examples</p> <p>A method performed on the body which does not enable a medical condition to be identified, but which may be of value in diagnosis is not considered as method of diagnosis. Thus, a method of taking a sample, or determining internal temperature or pH, does not identify a condition and would be considered as a patentable subject matter in view of Section 22.3 of the IP Code.</p> <p>A method of measuring the nitrogen monoxide content during exhalation requires the presence of the patient, hence it is considered to be a technical step practised on the human body. The other steps of the method - comparison with standard values, finding of a deviation, and attribution of the deviation to a clinical picture –were all held to be non-technical in nature, and so a claim like this is considered to be an unpatentable method of diagnosis.</p> <p>A fitness test, wherein the general physical state of an individual is determined, is not considered to be diagnostic if it is not intended to identify or uncover a pathology.</p> <p>Likewise, a method carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, may not be considered to satisfy the criterion “practised on the human or animal body”, because their performance does not necessitate the presence of the latter. By the same token, this criterion is neither complied with in respect of method steps carried out <i>in vitro</i> in a laboratory.</p>
	<p>7.4.3 <i>In vivo</i> testing of drugs</p> <p><i>In vivo</i> methods of testing pharmacological efficacy or toxicity of drugs, or experimental methods of investigating diseases in animals are not considered to be methods of diagnosis. However, if the method would cause suffering to the animal and the application does not disclose any potential medical use</p>

	<p>or medical research benefit, objection may be made as being incapable of industrial application, or as being contrary to public policy or morality.</p>
<p>Section 22.3, IP Code</p>	<p>8. FIRST MEDICAL USE</p> <p>When a substance is known, but its pharmacological properties are not disclosed in the art, first medical use maybe claimed in the form of a purpose-related product claim. The technical teaching being the novel and inventive purpose of the known substance.</p> <p>The concept of "first medical use" can only be applied to claims relating to known substances or compositions for use in therapy, surgery or diagnosis as referred to in Section 22.3 of the IP Code.</p> <p>A first medical use claim to the use of two different agents (both of which are known in the prior art for therapeutic use separately) for simultaneous, separate or sequential use in therapy is considered new, if there has been no disclosure of the use of the two agents together in therapy.</p> <p>A first medical use claim of the form “(substance X) for use in therapy” would be anticipated by any prior use of the substance in therapy. If any prior medical use is found, an amendment of the claim to the second medical use format is accepted. Determination on inventive step will also be focused on the claimed use vis-a-vis any prior use in the art.</p> <p>The drafting of first medical indication patents may take the following forms:</p> <ul style="list-style-type: none"> i) Compound/composition X for use in therapy; ii) Compound/composition X for use as a medicament; iii) Compound/composition X for use in the treatment of medical condition Y <p>The form of a first medical use claim aforecited is allowable for the first medical use of a substance or composition, provided there is support in the form of evidence for at least one medical use.</p> <p>The Swiss-type form of claim is also acceptable when claiming a first medical indication.</p>
	<p>9. “SECOND MEDICAL USE” CLAIMS</p> <p>In assessing applications with second medical use claims, it is important to understand how second medical use is presented within the context of the QUAMA provision.</p> <p>The concept of "second (further) medical use" can only be applied to claims relating to the subsequent use of known substances or compositions for the preparation of a medicament intended for therapy, surgery or diagnosis as referred to in Section 22.3 of the IP Code.</p> <p>If an application includes “method of treatment” claims, re-drafting of these claims into second medical use claim format (“Swiss-type”) does not constitute new matter and thus may be submitted anytime during examination stage.</p>

9.1 SWISS-TYPE CLAIMS

Swiss-type claims can be drafted according to any of the following formats:

- ✓ Use of a substance X in the manufacture of a medicament for the treatment of disease Y.
- ✓ Use of a substance X in the preparation of a medicament for the treatment of disease Y.
- ✓ Use of a substance X for the preparation of a pharmaceutical composition for the treatment of disease Y.

These types of claims are construed as an activity of formulating the medicament's active substance which constitutes the process for obtaining the medicament, which will pass the requirement of industrial applicability.

In a Swiss-type claim, it is considered that the intended purpose of the manufacture of the agent is the use of a known compound in the treatment of the human or animal body by surgery or therapy or in a diagnostic method.

Claims relating to the use of a substance for the manufacture of a medicament are permitted where the novelty is derived from the new pharmaceutical use and not from the product.

Under Section 22.3 of the IP Code, as amended, the following claims are not allowable:

- ✗ Method of treating disease Y by administering (a therapeutically effective amount of) a substance or composition X.
- ✗ Use of a substance or composition X for the treatment of disease Y.
- ✗ Use of a substance or composition X as an antibacterial (cardiovascular, bronchiolytic, etc.) agent.
- ✗ Use of a substance or composition X as a medicament for the treatment of disease Y.
- ✗ Use of substance or composition X for the method of treatment of disease Y.

The aforecited claims are considered as “methods of treatment”, thus not allowed by express provision of law.

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