

COMPARATIVE STUDY REPORT

ON

TRILATERAL PROJECT 12.4 INVENTIVE STEP

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I. Determining inventive step

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A. Judicial, legislative or administrative criteria or guidelines for determining inventive step

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1. Legislation

o Article 29(2) of the Patent Act

o Legislation  
European Patent Convention  
- EPC - New version (entry into force on 13 December 2007)  
Article 52 (patentable inventions)  
Article 56 (definition of inventive step)  
Article 54 (definition of novelty)  
Article 89 (effect of priority right)  
(See also Rule 65.1 PCT - Inventive Step or non-obviousness: approach to prior art)

o Title 35 of the United States Code section 103 (35 U.S.C. 103)  
Section 1.104 of Title 37 of Code of Federal Regulations (37 CFR 1.104)

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2. Guidelines

o Examination Guidelines Part II. Chapter 2. "Novelty and Inventive Step"  
2. Inventive step (Nonobviousness)

Guidelines for Examination in the European Patent Office (as published on December 2007).

o Guidelines for the Search  
\* B-VI, 1-6 (the state of the art)  
o Guidelines for Substantive Examination  
\* C-IV, 6 (state of the art)  
\* C-IV, 9 (test for novelty)  
\* C-IV, 11 (inventive step)  
\* C-IV-Annex (indicators for inventive step)  
\* C-V, (priority)  
o Guidelines for Opposition Procedure)  
\* D-V, 3.1 - 3.3 (state of the art)

o MPEP  
Sections 706.02(j) to 706.02(n), 2106 to 2107, 2141 to 2146, and 2163 of the Manual of Patent Examining Procedure (MPEP).

**NB. Assessment of inventive step**

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is a matter of case-by-case analysis. Therefore, no case law has been cited below. In this respect, the EPO would like to refer to the relevant sections of the Guidelines, which explicitly cite the case law to be taken into account in patent prosecution, and to the EPO publication "Case Law of the Boards of Appeal of the European Patent Office", 5th edition 2006. Both publications are available for download on the Internet site of the EPO.

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3. Background and purpose of the provision relating to inventive step

o The purport of the provision of Patent Act Article 29(2) is not to grant a patent to such inventions that were easily made by a person skilled in the art, since granting a patent to such inventions does not contribute to and even hampers the progress of technology.

(Examination Guidelines Part II. Chapter 2. Section 2.1)

o As regards the purpose of the notion of inventive step, it was considered improper that applicants whose alleged inventions, albeit new, presented only technical solutions which would have been obvious to any person skilled in the art, should acquire a monopoly right on "inventions" which do not go beyond the normal development in the relevant technical field.

o Guided by these considerations and owing to the fact that European patents are now granted for an ever growing number of Contracting States, the EPO has decided to apply a standard of inventive step based on a realistic, well-balanced approach, i.e., not too high, so as not to deny protection to valuable contributions to the known art and not too low so as to ensure a high presumption of validity of European patents.

o The general purpose behind the requirement of inventive step or nonobviousness is to limit patent rights to those innovations that in fact serve to advance the state of the useful arts.

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B. Claim interpretation criteria

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| <ul style="list-style-type: none"><li>o The scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent. In such case, an invention specified by a statement in one claim may be the same invention specified by a statement in another claim. (Article 36(5) of the Patent Act)</li><li>o The determining of a claimed invention should be made on the basis of the statements of the claim. Matters stated in the claim defining the claimed invention should be construed in the light of the description in the specification, the drawings and the common general knowledge as of the filing.<br/>The method of determining a claimed invention is as follows.<ul style="list-style-type: none"><li>(1) When the claim statements are clear, the determining of the claimed invention should be made just as stated in the claim. Terms or language in such a claim should be construed as what they normally mean.</li><li>(2) Even though the claim statements are clear, however, when terms or language used in the claim are defined or explained in the specification or the drawings, the definition or explanation should be considered when the terms or language are construed.</li><li>(3) If the claimed invention is not clear, even by referring to the</li></ul></li></ul> | <ul style="list-style-type: none"><li>o The claim(s) of a European patent application must define the matter for which protection is sought in terms of the technical features of the invention (Article 84 1st sentence, Rule 43 (1) EPC).</li><li>o The claims must be clear and concise and be supported by the description (Article 84, 2nd sentence EPC),</li><li>o Form and content of the claims are further defined in Rule 43 EPC.</li><li>o The terms of the claims determine the extent of the protection conferred by a European patent or patent application, the description and drawings being used to interpret the claims (Article 69 (1) EPC).</li><li>o Regarding the interpretation of claims for that purpose, the following more general rules apply (for details see Guidelines C-III, 4 on clarity and interpretation of claims):<ul style="list-style-type: none"><li>* The claims should be read with an attempt to make technical sense out of them. Such a reading may involve a departure from the strict literal meaning of the wording of the claims.</li><li>* Each claim should be read giving the words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise.</li></ul></li><li>o Any independent claim must clearly specify all the essential features needed to define the</li></ul> | <ul style="list-style-type: none"><li>o The U.S. practice is for the examiner to evaluate each independent and dependent claim on the basis of: statutory subject matter (35 U.S.C. 101); if the claim complies with the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph (written description, enablement); if the claim particularly points out and distinctly claims the subject matter applicant regards as his invention (35 U.S.C. 112, 2<sup>nd</sup> paragraph); is novel and the applicant has not lost his right to a patent (35 U.S.C. 102); and, is nonobvious subject matter (35 U.S.C. 103).</li><li>o Once the examiner has determined that the claim encompasses statutory subject matter, the examiner proceeds to evaluate the claim in regard to prior art and to determine whether the claim complies with the requirements of 35 U.S.C. 112.</li><li>o The examiner may reject the claim as being vague and indefinite, incomplete, or prolix. See MPEP 2173.05(a) to (v).</li></ul> |
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description in the specification, the drawings and the common general knowledge as of the filing, the determining of the claimed invention should not be conducted.

- (4) Even though there is inconsistency between an invention found in the claim and an invention described in the specification and the drawings, the determining and examination of an invention should not be made solely on the basis of the description in the specification and the drawings, disregarding the statements of the claim.

Even though they are described in the specification or the drawings, matters, not stated in the claim, should not be treated as they do exist in the claim when the determining of the claimed invention should be made. On the other hand, matters stated in the claim should be always considered and should not be treated as they do not exist in the claim.

(Examination Guidelines Part II.  
Chapter 2. "1.Novelty" Section  
1.5.1)

subject-matter of the invention, i.e. all features which are necessary to obtain the desired result or, expressed differently, which are necessary to solve the technical problem underlying the invention as claimed.

- o It is therefore the subject-matter of the claim so defined and considered as a whole which embodies the invention and forms the basis for assessing the inventive step involved.

1. Application of prior art to a claim with a preamble stating features necessary for definition of claimed subject matter followed by a characterizing portion stating those technical features to be protected

- o The scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent. In such case, an invention specified by a statement in one claim may be the same invention specified by a statement in another claim.

- o Rule 43 (1) (a) and (b) EPC defines the two-part form which a claim should adopt " wherever appropriate".
- o The first part should contain a statement indicating "the designation of the subject-matter of the invention" (i.e. the general technical category of apparatus, process etc.) to which

- o When the examiner evaluates an independent claim for patentability, he/she must: determine if the preamble is a limitation on the claim
- \* The determination of whether preamble recitations are structural limitations or mere statements of purpose or use can be resolved only on review

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(Article 36(5) of the Patent Act)

the invention relates, followed by a statement of "those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, are part of the prior art". This statement of prior art features applies only to independent claims and not to dependent claims.

- o The second part or "characterizing portion" should state the technical features for which, in combination with the features stated in the first part of the claim, protection is sought, i.e. the features on which the contribution to the art is based.
- o As indicated by Rule 43 EPC, the two-part formulation need be used only in appropriate cases. Generally speaking, a claim in two-part form must be regarded as appropriate if there exists a clearly defined state of the art from which the claimed subject-matter distinguishes itself by further technical features.
- o However, the nature of the invention may be such that this form of claim is unsuitable, e.g. because it would give a distorted or misleading picture of the invention or the prior art (Guidelines C-III, 2.3 with examples), or where a one-part claim would define the subject-matter claimed clearly and concisely by avoiding inappropriate and complex formulations.
- o If the indication of the prior art in the description allows the reader to see clearly which features of the claimed subject

of the entirety of the record to gain an understanding of what the inventors actually invented and intended to encompass by the claim. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction.

- o The Jepson claim format is permitted in the regulations, 37 CFR 1.75(e), which states that "[w]here the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order: (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known; (2) A phrase such as "wherein the improvement comprises;" and (3) Those elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion. The regulation is intended only as a strong recommendation, not as a mandatory requirement.
- o With a claim written in Jepson format, the preamble is considered to positively and clearly include all the elements

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- matter are, in combination, part of the prior art, the two-part form will not be insisted upon by the examiner (Guidelines C-III, 2.3.2),
- o The fact that the two-part form is not mandatory implies that the examiner is not legally bound to distinguish between state of the art and features added to it strictly according to the wording of the claims. Nor is the two-part formulation of a claim to be regarded as a binding statement of the applicant as to which features are prior art and which are the features characterising the invention.
  - o It is the subject-matter of the claim as a whole which embodies the invention and forms the basis for the assessment of inventive step.
  - o As regards the importance of the form of claim for assessing inventive step, the following is to be emphasized:
    - \* Whether the claim is in the one-part or two-part form makes no difference whatsoever to the scope of the claim.
    - \* Nevertheless, where the claim is in the two-part form, the examiner is entitled to use the prior art acknowledged in the preamble as a starting point for an obviousness objection, even if he does not know on which document (or other state of the art) this acknowledgement is based. If, however, the applicant states that he has made a mistake regarding the content of the preamble, he may be allowed to correct it and the
- or steps recited therein a part of the claimed combination.
- o The examiner may use the preamble of a Jepson type claim as the basis for a rejection stating the preamble is impliedly admitted as prior art.
  - o The implication, however, may be overcome by the inventor showing that the limitations contained in the preamble are the inventor's own invention and the inventor has not lost the rights to the invention under 35 U.S.C. 102 (b), (c) or (d).
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obviousness objection will  
then have to be reviewed  
accordingly.

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2. Determination of claimed  
scope and content

o See I. B. above.

o As already stated above (I.B, General observations), it is the subject-matter of the independent and dependent claims, defined by the essential technical features and considered as a whole, where necessary as interpreted in the light of the description and drawings, which embodies the invention and forms the basis for assessing the inventive step involved.

o The examiner reads the claim and determines the scope of the invention based on the technical subject matter defined in the claim. During examination, the words of the claim are given the broadest reasonable interpretation in light of the specification

o The examiner has the responsibility to make sure the wording of the claim is sufficiently definite to reasonably determine the scope.

o If the claims read in light of specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention and if the language is as precise as the subject matter permits, applicant has complied with 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

o Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex

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*parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).*

3. Dependent claim interpretation

o Claims are classified into independent form claims and dependent form claims. Independent form claims are those defined without referring to other claims, while dependent form claims are those which refer to other preceding claims. The two types of claims differ only in the form of description, and are treated in the same manner.

(Examination Guidelines Part I. Chapter 1. "Description Requirements of the Specification" Section 2.2.4, Article 36(6)(iv) of the Patent Act)

- o In accordance with Rule 43 (3) EPC, any claim stating the essential features of an invention, i.e. an independent claim, may be followed by one or more claims concerning "particular embodiments" of that invention, i.e. dependent claims which necessarily must include also the essential features of the invention, hence all the features of at least one independent claim.
- o Any claim which includes all the features of any other claim (in the same category) is termed a "dependent claim" (Rule 43 (4)). If the two-part form is used for the independent claim, dependent claims may relate to further details of features not only of the characterizing portion of the claim but also of the preamble (Guidelines, C-III. 3.6).
- o It should be noted that a reference to another claim does not necessarily imply that the claim containing the reference is in fact a dependent one, e.g. a claim referring to a claim of different category is not treated as a dependent claim but as an independent claim. Other examples are given: in Guidelines C-III, 3.8.
- o All dependent claims referring back to a single previous claim and those referring back to several previous claims must be grouped together to the extent

- o An applicant may submit a claim in "dependent form" referring back to and incorporating by reference a previous claim and adding some additional limitation.
- o A multiple dependent claim may also be submitted which refers back in the alternative to more than one preceding independent or dependent claims.
- o Furthermore, a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly.
- o There is no requirement that the limitation added in the dependent claims be an indispensable feature only that it adds an additional limitation or further defines a portion of the claim upon which it depends.
- o Effective November 1, 2007, the rules of practice for the examination of claims in an application (37 CFR 1.75) has been revised to provide that if the number of independent claims is greater than 5 or the number of total claims is greater than 25, the Office will require the applicant to submit an examination support document (ESD) complying with 37 CFR 1.265 covering all of the claims in the application. If applicant chooses not to file an ESD, the application must be amended to contain no more than 5 independent claims and no more than 25 total claims. [Note: In

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and the most appropriate way possible (Guidelines C-III, 3.5).

- o As regards the treatment of true dependent claims in the examination for inventive step, it should be noted that, in general, when the corresponding independent claim is allowable, the examiner will not concern himself unduly with the subject-matter of dependent claims, provided he is satisfied that they are truly dependent and thus in no way extend the scope of protection of the invention defined in the corresponding independent claim (Guidelines C-III, 3.5). If an independent claim is new and non-obvious, there is no need to investigate whether any claim dependent thereon involves an inventive step.

view of the preliminary injunction issued by the U.S. District Court for the Eastern District of VA on Oct. 31, 2007, the changes to the rules of practice in the claims and continuation final rules did not go into effect on Nov. 1, 2007.]

C. Basic approach applied in assessing inventive step e.g. test for non-obviousness, avoidance of ex post facto reasoning, and considering what the skilled man would have done starting from a given problem

- o Whether or not a claimed invention involves an inventive step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.
- o After determining what is described in a claimed invention and one or more cited inventions, one cited invention most suitable for the reasoning is selected. And comparison of the claimed

- o The underlying concept in assessing inventive step is that every invention must be the solution of a technical problem. If there were no technical problem, there could not be any solution and hence there would be no inventive step and thus no invention.
- o However the assessment of the technical problem can itself be as difficult as assessing the inventive step, and great care must be taken to avoid certain pitfalls which occur with this approach.
- o First, it must be highlighted that the European Convention does not require that an invention be a (technical) improvement over

- o The question of nonobviousness must be determined as of the "time the invention was made."
- o The use of hindsight or evaluation in the context of skills developed by the evaluator or skilled artisan after the date of the invention have no place and must be ignored in the determination of nonobviousness,
- o The U.S. Supreme Court in *KSR International Co. v. Teleflex Inc. (KSR)*, 82 USPQ2d 1385, 1391 (2007) reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere*. The basic factual inquiries of *Graham v. John Deere* are: (1) determining the scope and contents of the prior art; (2) ascertaining the differences

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invention with a cited invention is made, and the identicalness and the difference in matters defining the inventions are clarified. Then, the reasoning for lacking an inventive step of the claimed invention is attempted on the basis of contents of the selected invention above, other cited inventions (including well-known or commonly used art) and the common general knowledge.

The reasoning can be made from various and extensive aspects. For example, the examiner evaluates whether the claimed invention falls under a selection of an optimal material, a workshop modification of design, a mere juxtaposition of features on the basis of a cited inventions, or whether the contents of cited inventions disclose a cause or a motivation for a person skilled in the art to arrive at the claimed invention.

If advantageous effects of the claimed invention over a cited invention can be clearly found in the description in the specification, etc., it is taken into consideration as facts to support to affirmatively infer the involvement of an inventive step.

When the reasoning can be made as a result of the above method, the claimed invention should be denied its inventive step. When the reasoning cannot be made, the claimed invention should not be denied its involvement of an inventive step.

the prior art . Consequently the technical problem may be reduced to that of finding an alternative to a known solution. The question as to whether this alternative involves an inventive step can then only be decided using such criteria as mentioned in E below.

o Second, it must be remembered that the objective problem solved by the invention may be different from that recorded in the description of the invention. An examiner may then require reformulation of the problem in the light of facts appearing in the prior art revealed in the course of the proceedings, in particular the prior art cited in the search report, which may be different from that of which the applicant was actually aware at the time the application was filed and which may put the invention in an entirely different perspective from that apparent from reading the application only (Guidelines, C-IV, 11.7.2).

o Equally the situation arises where the solution to the stated problem appears to be trivial or obvious from the prior art, but a careful analysis of the problem reveals that it is in fact the very statement of the problem itself which is the crux of the invention so that logically the claimed invention must involve an inventive step because it is a step from something which was not known.

o Finally, it should be remembered that once a new idea has been formulated, it can often be shown theoretically how it might be

between the prior art and the claims in issue; and (3) resolving the level of ordinary skill in the art while taking into account secondary considerations.

o The examiner conducts the search of the pertinent art where one can reasonably be expected to look for a solution to the problem which the device attempts to solve.

o The Supreme Court in *KSR* noted that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Exemplary rationales that may support a conclusion of obviousness include:

- (1) Combining prior art elements according to known methods to yield predictable results;
- (2) Simple substitution of one known element for another to obtain predictable results;
- (3) Use of known technique to improve similar devices (methods, or products) in the same way;
- (4) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (5) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (6) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary

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o The reasoning can be made from various and extensive aspects. Examples are as follows.

(1) Selection of an optimal material, workshop modification of design, mere juxtaposition of features

Selection of an optimal material, workshop modification of design, etc.

Among exercises of ordinary creativity of a person skilled in the art are a selection of an optimal material from publicly known materials which achieve a specific object, an optimization of a numerical value range, a replacement with equivalents, and a workshop modification of design in applying specific technology. When the difference of the claimed invention in comparison falls only under these categories, it is usually considered that a person skilled in the art could have easily arrived at it, unless otherwise there is another ground for inferring inventive step.

Mere juxtaposition of features

If matters defining an invention are not linked each other functionally or operationally and the invention is a combination of each matter (mere juxtaposition of features), the invention is deemed as a mere exercise of ordinary creativity of a person skilled in the art, unless otherwise there is another ground for inferring inventive

arrived at, starting from something known by a series of apparently easy steps. The examiner should be vary of ex post facto analysis of this kind.

o In practice, in order assess inventive step in an objective and predictable manner, an examiner will apply the so-called "problem-and-solution approach, which consists in three successive steps, namely:

- 1) Determining the "closest prior art"
- 2) Establishing the "objective technical problem" to be solved
- 3) Considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person (the "could-would" approach).

o The "closest prior art" in the first step is that combination of features disclosed in one single reference which constitutes the most promising starting point for an obvious development leading to the invention. It does not include later published European applications. In practice, the closest prior art is generally that which corresponds to a similar use in the same or a closely related technical field. It must be assessed from the skilled person's point of view on the day before the filing or priority date valid for the claimed invention (Guidelines C-III, 11.7.1).

o The "objective technical problem" to be solved in the second step means the aim and task of modifying or adapting the closest

skill in the art;

(7) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

- o See MPEP 2143 for discussions of each rationale along with examples illustrating how the cited rationales may be used to support a finding of obviousness.
- o The list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.

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step.

(2) Probable cause or motivation

Relation of technical fields

An attempt to apply a technical means in a related technical field in order to solve a problem is a mere exercise of ordinary creativity of a person skilled in the art. A replaceable or addable means in a related technical field, for example, can be a strong ground for the reasoning that a person skilled in the art would have been led to a claimed invention.

Similarity of a problem to be solved

A close similarity of a problem to be solved can be a strong ground for the reasoning that a person skilled in the art would be led to a claimed invention by applying or combining cited inventions.

When a cited invention does not intend a similar problem to be solved to that of a claimed invention, further examination based on the state of the art should be conducted whether a problem to be solved is obvious or whether it would have been easily conceived.

Even based on a problem to be solved of a cited invention which is different from that of a claimed invention, the inventive step of the claimed invention can be denied regardless of the difference in problems, if the reasoning can properly be made

prior art to provide the technical effects that the claimed invention provides over the closest prior art. In practice, an examiner will study the application in the light of the closest prior art and the difference between both in terms of features (the so-called "distinguishing features"). If the technical problem derived in this way is different from the technical problem as defined by the applicant in the application, the examiner will redefine the latter. It is to be noted that the objective technical problem must be so formulated as not to contain pointers to the technical solution, in order to avoid ex post facto view in the assessment of inventive activity (Guidelines, C-III, 11.7.2).

- o The "could-would" approach in the third step means that the examiner will consider whether there is any teaching in the prior art as a whole that **could** (and not simply would) have prompted the skilled person, faced with the objective to adapt or modify the closest prior art in the hope of solving the objective technical problem or in expectation of some advantage or improvement (Guidelines, C-IV, 11.7.3). Thus, the question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim and having regard to the art known at that date, it would have been obvious to the skilled person to arrive at something falling within the terms of the

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that a person skilled in the art could have easily arrived at the matters defining the claimed invention in a different way of thinking from the problem-solution of the claimed invention.

This also applies to inventions wherein any problem to be solved cannot be identified, for example, inventions based on a discovery by trial and error.

Similarity of function, work or operation

If a close similarity in function, work or operation exists between a claimed invention and a cited invention or between cited inventions, there can be a well-founded reasoning that a person skilled in the art would have been led to the claimed invention by applying and combining the cited inventions.

Suggestions shown in the cited inventions

Suggestions shown in the contents of cited inventions relevant to a claimed invention can be a strong ground for the reasoning that a person skilled in the art would have been led to the claimed invention.

(3) Advantageous effects

If an advantageous effect compared to cited inventions can clearly be identified from descriptions in the specification and the drawings, it should be

claim (Guidelines, C-IV, 11.4).  
o The invention, however, must be considered as a whole. If a claim consists of a "combination of features", and the functional interaction between them achieves a combined technical effect that is different from, e.g. greater than, the sum of the technical effects of the individual features, then the whole subject matter claimed is non-obvious, even if each feature, taken by itself, would be obvious. If no such synergistic effect exists, there is no more than a mere aggregation of features which does not involve an inventive step (Guidelines, C-IV, 11.5).

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taken into consideration as a fact to support to affirmatively infer its inventive step. An advantageous effect compared to cited inventions means an effect which is advantageous in comparison with an effect of a cited invention, among the effects derived from the matters defining a claimed invention.

(Examination Guidelines Part II.  
Chapter 2. Section 2.4, 2.5)

D. Criteria for determining the ability to apply prior art from non-analogous technical fields

- o Whether or not a claimed invention involves an inventive step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.
- o The reasoning can be made from various and extensive aspects.
- o A close similarity of a problem to be solved can be a strong ground for the reasoning that a person skilled in the art would be led to a claimed invention by applying or combining cited inventions.  
When a cited invention does not intend a similar problem to be solved to that of a claimed invention, further examination based on the state of the art should be conducted whether a

- o The "state of the art" for the purpose of considering inventive step is to be understood as concerning such kind of information as is relevant to the technical field of the claimed invention, including common general knowledge and normal means for routine work and experimentation.
- o However, in practice, it is accepted that each invention is addressed to a person specially skilled in the technical field to which the invention relates. If the definition of the "objective problem to be solved" prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field will be the person qualified to solve the problem.
- o The skilled man can thus be drawn to other relevant, but not necessarily analogous, fields and it is then assumed that the "skilled man" has all the specialized knowledge of both fields and his assessment of inventive step is based upon the

- o For purposes of 35 U.S.C. 103, prior art can be either in the field of applicant's endeavor or be reasonably pertinent to the particular problem with which the applicant was concerned. Furthermore, prior art that is in a field of endeavor other than that of the applicant or solves a problem which is different from that which the applicant was trying to solve, may also be considered for the purposes of 35 U.S.C. 103.
- o The issue is whether the skilled artisan would have looked at the other field for assistance in designing the invention or solving the problem.
- o Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious

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	<p>problem to be solved is obvious or whether it would have been easily conceived.</p> <ul style="list-style-type: none"><li>o If a close similarity in function, work or operation exists between a claimed invention and a cited invention or between cited inventions, there can be a well-founded reasoning that a person skilled in the art would have been led to the claimed invention by applying and combining the cited inventions.</li><li>o Suggestions shown in the contents of cited inventions relevant to a claimed invention can be a strong ground for the reasoning that a person skilled in the art would have been led to the claimed invention.</li></ul> <p>(Examination Guidelines Part II. Chapter 2. Section 2.4)</p>	<p>combined prior art.</p>	<p>to one of ordinary skill in the art.</p> <ul style="list-style-type: none"><li>o The focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense.</li></ul>
<hr/>			
<p><u>E. Criteria for determining the differences between the prior art and the claims</u></p>			
<hr/>			
<p><u>1. Combinations of prior art</u></p>			
<hr/>			
<p>a. <u>Requirements, if any, of a teaching or suggestion to combine features</u></p>	<ul style="list-style-type: none"><li>o Selection of an optimal material, workshop modification of design, etc.</li></ul> <p>Among exercises of ordinary creativity of a person skilled in the art are a selection of an optimal material from publicly known materials which achieve a specific object, an optimization of a numerical value range, a</p>	<ul style="list-style-type: none"><li>o It is permissible to combine the disclosure of one or more documents, parts of documents or other pieces of prior art with the closest prior art. However, it is not enough to merely say that the sum of the claimed features is present in the cited documents. The examiner must give proper reasoning as to why the skilled man would (not, could)</li></ul>	<ul style="list-style-type: none"><li>o The Supreme Court in <i>KSR</i> recognized that the teaching-suggestion-motivation (TSM) rationale was one of a number of valid rationales that could be used to determine obviousness. Other rationales (set forth in C above) may support a conclusion of obviousness.</li></ul>

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replacement with equivalents, and a workshop modification of design in applying specific technology. When the difference of the claimed invention in comparison falls only under these categories, it is usually considered that a person skilled in the art could have easily arrived at it, unless otherwise there is another ground for inferring inventive step.

o Mere juxtaposition of features

If matters defining an invention are not linked each other functionally or operationally and the invention is a combination of each matter (mere juxtaposition of features), the invention is deemed as a mere exercise of ordinary creativity of a person skilled in the art, unless otherwise there is another ground for inferring inventive step.

o Relation of technical fields

An attempt to apply a technical means in a related technical field in order to solve a problem is a mere exercise of ordinary creativity of a person skilled in the art. A replaceable or add-able means in a related technical field, for example, can be a strong ground for the reasoning that a person skilled in the art would have been led to a claimed invention.

o Similarity of a problem to be solved

combine the features.

- o Where the invention is a solution to a plurality of independent "partial problems", it is necessary to separately assess, for each partial problem, whether the combination of features solving the partial problem is obviously derivable from the prior art. In this case, a different prior art document can be combined with the closest prior art for each partial problem (Guidelines, C-IV, 11.8).

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A close similarity of a problem to be solved can be a strong ground for the reasoning that a person skilled in the art would be led to a claimed invention by applying or combining cited inventions.

When a cited invention does not intend a similar problem to be solved to that of a claimed invention, further examination based on the state of the art should be conducted whether a problem to be solved is obvious or whether it would have been easily conceived.

Even based on a problem to be solved of a cited invention which is different from that of a claimed invention, the inventive step of the claimed invention can be denied regardless of the difference in problems, if the reasoning can properly be made that a person skilled in the art could have easily arrived at the matters defining the claimed invention in a different way of thinking from the problem-solution of the claimed invention.

This also applies to inventions wherein any problem to be solved cannot be identified, for example, inventions based on a discovery by trial and error.

- o Similarity of function, work or operation

If a close similarity in function, work or operation exists between a claimed invention and a cited invention or between cited inventions, there can be a well-founded

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reasoning that a person skilled in the art would have been led to the claimed invention by applying and combining the cited inventions.

- o Suggestions shown in the cited inventions

Suggestions shown in the contents of cited inventions relevant to a claimed invention can be a strong ground for the reasoning that a person skilled in the art would have been led to the claimed invention.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(1)(2))

b. Restrictions, if any, on the ability to modify a prior art teaching; e.g. the number of prior art teachings that can be combined

- o There is no particular restrictions of the number of prior art teachings that can be combined in the examination of inventive step under Article 29 (2) of the Patent Act.

- o There is no restriction on the number of prior art teachings which may be combined.
- o However, it must be kept in mind that the fact that more than one disclosure must be combined with the closest prior art in order to arrive at a combination of features may be an indication of the presence of an inventive step. On the other hand, the more teachings which are being combined, the more likely it is that ex post facto analysis or lack of proper reasoning is involved.
- o In determining whether it would be obvious to combine two or more distinct disclosures, the examiner should also consider:
  - 1) whether their content is such as to make it likely or unlikely that the skilled person would combine them;
  - 2) whether the disclosures come

- o There are no restrictions as to the number of prior art references that might be combined for rejecting a claim under 35 U.S.C. 103.

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from similar, neighboring or remote technical fields;  
3) whether there is a reasonable basis to associate these disclosures with one another (i.e., a document contains a clear and unmistakable reference to another document) (Guidelines, C-IV, 11.8).

2. Problem of common general knowledge  
i.e. the question as to whether the examiner, if he is reasonably certain that a given feature is common general knowledge but cannot prove it (because there is no supporting document), is entitled to refuse a claim

a. On the basis of that knowledge alone

o Whether or not a claimed invention involves an inventive step is determined as follows: After determining what is described in a claimed invention and one or more cited inventions, one cited invention most suitable for the reasoning is selected. And comparison of the claimed invention with a cited invention is made, and the identicalness and the difference in matters defining the inventions are clarified. Then, the reasoning for lacking an inventive step of the claimed invention is attempted on the basis of contents of the selected invention above, other cited inventions (including well-known or commonly used art) and the common general knowledge.

o The Examining Division may, in a first step, object to a claim on the basis of common general knowledge without providing a documentary support for this assertion, If, however, the applicant disagrees with the assertion, the Examining Division should then cite a reference in support of the objection.  
o If the examiner is unable to produce documentary evidence, he should raise an objection to the claim only if he is certain of his position. In all other cases, he should not press the objection.  
o Since the prosecution file is open to public inspection, applicants will be aware that such an objection could be successful if, in subsequent

o In certain circumstances where appropriate, an examiner may take official notice of facts not in the record or rely on "common knowledge" in making a rejection, however, such rejections should be judiciously applied.  
o It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection is based. See *In re Zurko*, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001).

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(Examination Guidelines Part II.  
Chapter 2. Section 2.5(2))

- o "The common general knowledge" means technologies generally known to a person skilled in the art (including well-known or commonly used art) or matters clear from empirical rules.  
"Well-known art" means technologies generally known in the relevant technical field, e.g., many prior art documents, those widely known throughout the industry, or those well-known to the extent needless to present examples. "Commonly used art" means well-known art which is used widely.

(Examination Guidelines Part II.  
Chapter 2. "1.Novelty" Section  
1.2.4(3))

- o Since well-known or commonly used art is important material constituting the state of the art which can be a ground for a notice of reasons for refusal, well-known or commonly used art should be accompanied with an exemplary document insofar as possible except when it is so well-known that any evidential document seems unnecessary, regardless of whether it is used as a basis to determine the cited invention or to determine the knowledge (the state of the art including the common general knowledge) or the ability (the ability to use ordinary technical means for research and

opposition proceedings, an opponent is able to provide evidence that the examiner rightly raised the obviousness objection.

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development or the ordinary creativity) of a person skilled in the art if an examiner refers to well-known or commonly used art.

(Examination Guidelines Part II. Chapter 2. Section 2.8(2))

- o If an applicant admits in a specification that a technology presented as prior art is publicly known prior to the filing of the application, the technology may be properly cited as the state of the art at the time of filing, in determining inventive step of a claimed invention.

(Examination Guidelines Part II. Chapter 2. Section 2.8(3))

b. On the basis of that knowledge combined with one or more published pieces of prior art

- o See E.2.a. above.

- o The same reasoning applies as for E.2.a.

- o When making a rejection, the examiner may combine prior art reference with official notice or "common knowledge."
- o If official notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge.
- o If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).
- o The applicant should be presented

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with the explicit basis on which the examiner regards the matter as subject to official notice so as to adequately traverse the rejection in the next reply after the Office action in which the common knowledge statement was made.

- o To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b).
- o If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

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3. Criteria for evaluating differences between the prior art and the invention in regard to:

- NB. The first decisive test for subsections "a" to "d" below is the novelty test. A sub-range will be considered novel if:
- 1) it is clearly narrower than the known range,
  - 2) it is sufficiently removed from any specific example in the prior art and from the end-points of the known range, and
  - 3) it is not an arbitrary specimen

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from the prior art (Guidelines, C-IV, 9.8).

a. Temperature or other ranges

- o Among exercises of ordinary creativity of a person skilled in the art are a selection of an optimal material from publicly known materials which achieve a specific object, an optimization of a numerical value range, a replacement with equivalents, and a workshop modification of design in applying specific technology. When the difference of the claimed invention in comparison falls only under these categories, it is usually considered that a person skilled in the art could have easily arrived at it, unless otherwise there is another ground for inferring inventive step.

(Examination Guidelines Part II. Chapter 2. Section 2.5(1))

- o Non-obviousness of sub-ranges or overlapping ranges will depend on whether they are used for a different and non-obvious purpose or whether they involve a new, surprising effect or unexpected advantage.
- o On the other hand, mere substitutions, selections of equally likely alternatives or extrapolations from the known art, or any choice from a limited range of possibilities that could be arrived at by routine trial and error or normal design procedures will be rejected for lack of inventive activity.

- o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.
- o Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 105 USPQ 233, 235 (CCPA 1955).
- o A claim may be patentable where changes in temperature or other ranges produce a new or unexpected result which is different in kind and not merely degree.
- o This is referred to as "critical" ranges. The applicant has the burden of proving such criticality.

b. Shapes or configurations

- o See E.3.a. above.

- o The same reasoning applies as for E,3,a,

- o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.
- o There would be no inventive step where the difference between the claimed invention and the prior art is a change in shape or configuration that produced no

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unusual or unexpected result.  
o The court in *In re Dailey*, 149 USPQ 47 (CCPA 1966) held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.

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c. Materials or parts

o See E.3.a. above.

o The same reasoning applies as for E,3,a,

o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.  
o A claimed invention differing from the prior art by a different material with the selection of the material merely selected on the basis of suitability for the intended use, would not be considered to contain an inventive step in absence of a showing of an unexpected result flowing from the change in material.

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d. Sizes, ratios or amounts

o See E.3.a. above.

o The same reasoning applies as for E,3.a.

o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.  
o There would be no inventive step where the difference between the claimed invention and the prior art is a change in size, ratio or an amount of an element and these elements perform in combination the same function as set forth in the prior art without giving an unexpected result.  
o The Court in *Gardner v. TEC*

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*Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 225 USPQ 232 (1984), held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

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e. Reversed elements or parts

o See E.3.a. above.

o The same reasoning applies as for E.3.a,

o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.

o A claimed invention differing from the prior art by a reversal of elements or parts that operate in the same manner, would not be considered to contain an inventive step.

o In *In re Gazda*, 194 USPQ 400 (CCPA 1955), the prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel. The Court held that the mere reversal of such movement, so the clock moves with the wheel would have been an obvious expedient.

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f. Omitted elements or parts

o See E.3.a. above.

o If the omission is merely for commercial reasons i.e. a cheaper device with a consequent loss of quality, there is no inventive step.

o If the omission results surprisingly in an equal or even better quality, or successfully

o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.

o A claimed invention differing from the prior art by the elimination of a element and its

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goes totally against the current technical opinion then this is taken as a positive indication for an inventive step.

function would not be considered to contain an inventive step in absence of a showing of an unexpected result flowing from such omission.

- o The Court in *In re Larson*, 144 USPQ 347 (CCPA 1965) held that the omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.
- o Note that the omission of an element and retention of its function is an indicia of non-obviousness. See *In re Edge*, 149 USPQ 556 (CCPA 1966).

g. Change or limitation of use

- o See E.3.a. above.
- o Even if the medicinal use of the claimed medicinal invention differs from the medicinal use of the cited invention, when the relevance of the working mechanism between both has been derived from the publicly known art or common general knowledge at the time of filing, the inventive step of the medicinal invention of the present patent application is usually denied, unless otherwise there is another ground for inferring inventive step such as advantageous effect or the like.

(Examination Guidelines Part VII. Chapter 3. "Medicinal Inventions" Section 2.3.1.1(1))

- o For inventions, other than in chemistry, the new use of a known method does not involve an inventive step unless a new surprising effect is involved.
- o Similarly, a new use of a known product might be inventive if some technical difficulty were simultaneously overcome.
- o To the latter point, however, attention is called to the special regimen for substances or compositions used in the surgery, therapy or diagnostic methods practiced on the human or animal body as defined in Article 53 (c) EPC.
  - 1) Such substances or compositions may be patented if they have not been previously disclosed for use in these methods ("first medical use", Article 54 (4) EPC)
  - 2) If the substances or compositions are already known to have been used in a "first medical use", they may still be

- o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.
- o A claimed invention differing from the prior art by a change or limitation in the use which is merely analogous to the uses of the prior art would not constitute an inventive step absent a showing of an unexpected result flowing from that change or limitation of use.

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patentable under Article 54 (5) EPC for any "second or further use" in these methods, provided said use is novel and inventive (details are given in the Guidelines, C-IV, 4.8).

h. Selection invention

- o Where an invention with a generic concept is expressed in a cited reference, an invention with more specific concept selected from the generic concept is called "selection invention", if it is novel over the generic invention and pertains to a technical field in which an effect of a product is difficult to understand from its structure. Where an invention is expressed as alternatives either in form or de facto in a cited reference, an invention selected from a group of inventions each of which is identified by supposing that each of the alternatives is a matter to define each of such inventions is also called "selection invention", if it is novel over the alternatives and pertains to a technical field in which an effect of a product is difficult to understand from its structure. Thus, an invention can be a selection invention, if it is not an invention described in a publication.
- o A selection invention involves an inventive step, when it generates an advantageous effect which is qualitatively different or qualitatively the same but quantitatively prominent in comparison with that of an invention with a generic concept
- o The subject-matter of selection inventions differs from the closest prior art in that it represents selected sub-sets or sub-ranges. The usual criteria for the presence of an inventive step for a particular product or particular method selected, from a much wider known range of products or methods, is that an unexpected advantage or effect occurs.
- o If the selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection, then an inventive step is accepted (this technical effect occurring within the selected range may also be the same effect as attained with the broader known range, but to an unexpected degree).
- o Consequently, non-obviousness will depend on whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.
- o The question of obviousness must be resolved on the basis of the factual inquiries enunciated by the Court in the *Graham v. John Deere* decision.
- o Where a previously disclosed invention contains a broad range of components or ideas, a selection invention having an inventive step can occur where particular components or subordinate ideas are chosen and show a special significance or unexpected result and there was nothing cited in the art to suggest the criticality of the claimed components or subordinate ideas. However, as noted by the Supreme Court in *KSR*, if "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp [and if] this leads to the anticipated success, it is likely that the product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR*, 82 USPQ2d at 1397.

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in a cited invention, neither of which is foreseen by a person skilled in the art from the state of the art nor disclosed in a cited reference.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3) )

i. Others

o No other comments.

o No other comments.

o No other comments.

4. Indication of problem to be solved

o A close similarity of a problem to be solved can be a strong ground for the reasoning that a person skilled in the art would be led to a claimed invention by applying or combining cited inventions.

When a cited invention does not intend a similar problem to be solved to that of a claimed invention, further examination based on the state of the art should be conducted whether a problem to be solved is obvious or whether it would have been easily conceived.

Even based on a problem to be solved of a cited invention which is different from that of a claimed invention, the inventive step of the claimed invention can be denied regardless of the difference in problems, if the reasoning can properly be made that a person skilled in the art could have easily arrived at the matters defining the claimed invention in a different way of thinking from the problem-solution of the claimed invention.

This also applies to inventions wherein any problem to be solved cannot be identified, for

o The problem to be solved is viewed objectively by the Examiner based upon his full knowledge of the application and the relevant prior art. Here, it must be kept in mind that the problem viewed objectively is not necessarily the same as that the one mentioned by the applicant in his description.

o To this effect, the examiner studies the application and the closest prior art to find out the differences between them in terms of features (either structural or functional).

o Features which cannot be seen to make any contribution, either independently or in combination with other features, to the technical character of the invention are no relevant for the assessment of inventive step.

o However, where the claim refers to an aim to be achieved in a non-technical field, this may legitimately appear in the formulation of the problem as part of the framework of the technical problem to be solved (Guidelines, C-IV, 11.7.2).

o It may happen that the problem itself is judged to be new and to involve an inventive step. In

o In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. See 35 U.S.C. 103(a).

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example, inventions based on a discovery by trial and error.

(Examination Guidelines Part II. Chapter 2. Section 2.5(3) )

such case, the solution to the problem as expressed in the claims is deemed to involve an inventive step, unless the solution would inevitably be arrived at as an obvious solution to another problem (the so-called "one-way street" situations).

5. Indication of advantage of claimed invention

- o If an advantageous effect compared to cited inventions can clearly be identified from descriptions in the specification and the drawings, it should be taken into consideration as a fact to support to affirmatively infer its inventive step. An advantageous effect compared to cited inventions means an effect which is advantageous in comparison with an effect of a cited invention, among the effects derived from the matters defining a claimed invention.
- o Reasoning is attempted by confirming and taking into consideration an advantageous effect, if any, of a claimed invention compared to cited inventions. It should be noted that, regardless of advantageous effects, inventive step may be denied by the uncontestable reasoning that a person skilled in the art could have easily arrived at a claimed invention.
- o However, when the advantageous effect compared to the cited invention so remarkable that it cannot be foreseen by a person skilled in the art from the state of the art, there may be cases where the inventive step is affirmed.

- o The EPC does not require explicitly or implicitly that an invention, to be patentable, must entail some technical progress or even any useful effect. Nevertheless, advantageous effects, if any, with respect to the state of the art, should be stated in the description (Rule 42 (1) (c) EPC), and any such effects are often important in determining whether an invention is obvious or not (Guidelines, C-IV, 1.3).
- o However, if the invention is a foreseeable disadvantageous modification of the closest prior art that the skilled person could clearly predict and assess, and if this predictable disadvantage is not accompanied by an unexpected technical advantage, then the claimed invention does not involve an inventive step.
- o Similar considerations apply where an invention is merely the result of an arbitrary non-functional modification of a prior art device or a mere arbitrary choice from a host of possible solutions (Guidelines, C-IV, 11.9.1).

- o An advantage is not required in addition to nonobviousness.
- o A claim that contains language setting forth an advantage of the claimed invention over the prior art does not afford the effect of a distinguishing limitation without further structure in the claim and therefore would not constitute an inventive step. Note that a *prima facie* obviousness is not rebutted by merely recognizing additional advantages or latent properties present in the prior art. See *Lantech Inc. v. Kaufman Co. of Ohio Inc.*, 12 USPQ2d 1076, 1077 (Fed. Cir. 1989)(unpublished) ("The recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention.")

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(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3))

6. Comparative test

o Where advantageous effects compared to cited inventions are described in a specification, or where advantageous effects are not explicitly described but can be inferred from the statements in the specification or the drawings by a person skilled in the art, the effects asserted in a written argument or verified in experimental results should be considered. However, the effects asserted which are not described in the specification and that a person skilled in the art couldn't deduce from the description of the specification or the drawings should not be taken into consideration.

o See II.D,2,

o Comparative test are usually submitted as rebuttal evidence showing an unexpected result once the USPTO has established a case of *prima facie* obviousness in view of the prior art.  
o The comparative test data must be between the claimed invention and the closest prior art which is commensurate in scope with the claims. See MPEP 716.02(b), subsection III.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3) )

7. Unexpected result

a. Cases where an unexpected result is an essential criterion for unobviousness (selection inventions comprising the combination of known elements)

o Even though a reasoning seems to be possible that a person skilled in the art could have easily arrived at a claimed invention because of the close similarity between the matters defining a cited invention and the ones defining a claimed invention or because of a combination of plural cited inventions, the inventive step should be positively inferred if a claimed invention has an advantageous effect,

o For combination inventions (i.e., inventions based on a set of known technical features) a functional interaction between the features must achieve a combined technical effect which is different from, e.g. greater than, the sum of the technical effects of the individual features (Guidelines, CI-V, 11.5).  
o For selection inventions, (i.e., inventions based on sub-sets or sub-ranges selected from known

o If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case.  
o Rebuttal evidence may include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. A showing of unexpected results must be based on evidence, not argument or speculation.

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	<p>qualitatively different or qualitatively the same but quantitatively prominent in comparison with those of cited inventions, and if the advantageous effect cannot be foreseen by a person skilled in the art from the state of the art.</p>	<p>sets or ranges), the selection must be connected with a particular technical effect for which there is no hint in the prior art leading the skilled man to the selection (Guidelines, C-IV, 11.11).</p> <p>o However, if, having regard to the state of the art, it would have been obvious for a skilled person to arrive at something falling within the terms of a claim (i.e., if the lack of alternatives creates a "one-way street" situation), then the unexpected effect is merely a "bonus effect" which does not confer inventiveness to the claim (Guidelines, C-IV, 11.9.3).</p>	<p>o Unexpected results are usually presented in cases involving proportions, ranges, chemical purity, processes and selection inventions as evidence of nonobviousness.</p> <p>o Without evidence of an unexpected result. The invention would be obvious in view of the prior art that teaches the broad concept, range, proportion, etc.</p> <p>o If the prior art compound does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed compound from the prior art. <i>In re Dillon</i>, 16 USPQ2d 1897 (Fed. Cir. 1991).</p>
<p>b. <u>Cases where it is merely one of a number of relevant secondary criteria</u></p>	<p>o If an advantageous effect compared to cited inventions can clearly be identified from descriptions in the specification and the drawings, it should be taken into consideration as a fact to support to affirmatively infer its inventive step.</p>	<p>o An unexpected and/or surprising result may be an additional useful criterion when comparing a claimed invention with the prior art.</p>	<p>o Unexpected results is just one factor that has to be taken into account when determining obviousness.</p> <p>o The determination of obviousness is made by considering the totality of the evidence taking into account any secondary considerations and the presented unexpected result. Once the applicant has presented rebuttal evidence, the examiner should reconsider any initial obviousness determination in view of the entire record. All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability. The Office action should clearly communicate the Office's findings and conclusions, articulating how the conclusions are supported by the findings. See MPEP 2141,</p>

(Examination Guidelines Part II. Chapter 2. Section 2.5(3) )

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subsection V.

c. Does an unexpected effect (result) have to be advantageous to constitute an inventive step?

o Even though a reasoning seems to be possible that a person skilled in the art could have easily arrived at a claimed invention because of the close similarity between the matters defining a cited invention and the ones defining a claimed invention or because of a combination of plural cited inventions, the inventive step should be positively inferred if a claimed invention has an advantageous effect, qualitatively different or qualitatively the same but quantitatively prominent in comparison with those of cited inventions, and if the advantageous effect cannot be foreseen by a person skilled in the art from the state of the art.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3) )

o The practice is to require the effect to be "unexpected", i.e. that it could not have been predicted. The requirement is not that the effect has to be advantageous.

o Unexpected results may be presented by the applicant as evidence to rebut a *prima facie* showing of obviousness. The evidence presented must show that the result is new and unexpected. USPTO practice does not require the unexpected result to be advantageous to constitute an inventive step.

8. Others

o No other comments.

o No other comments.

o No other comments.

F. Resolving the level of ordinary skill

1. A person skilled in the art, an average expert

a. Amount of knowledge and skill expected

o A person skilled in the art is able to comprehend all technical matters in the state of the art in the field to which a claimed invention pertains at the time of

o The person skilled in the art is presumed  
\* to be an ordinary practitioner aware of what was common general knowledge in the art

o The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be

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filing as his/her own knowledge.

In addition, a person skilled in the art is supposed to be able to comprehend all technical matters in the field of technology relevant to a problem to be solved by an invention as his/her own knowledge.

(Examination Guidelines Part II.  
Chapter 2. Section 2.2(2))

at the relevant date,

- \* to have access to everything in the state of the art, in particular the documents cited in the search report,
- \* to have at his disposal the normal means and capacity for routine work and experimentation, and
- \* to possess the general technical knowledge appropriate to his assumed education and experience.

- o If the problem prompts the skilled person in the art to seek its solution in another technical field, the specialist of that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability (C-IV, 11.3).
- o The state of the art to be considered by the person skilled in the art when examining for inventive step includes not only that in the specific field of the application or patent but also that in related fields or neighboring fields and, where appropriate, in the broader general field which encompasses them.
- o On the other hand, the skilled man is not expected to be familiar with the prior art in a remote technical field.

considered in determining the level of ordinary skill in the art may include:

- (1) "type of problems encountered in the art;"
- (2) "prior art solutions to those problems;"
- (3) "rapidity with which innovations are made;"
- (4) "sophistication of the technology; and"
- (5) "educational level of active workers in the field."

In a given case, every factor may not be present, and one or more factors may predominate." *In re GPAC*, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995).

- o In addition to the above factors, examiners may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Court has stated that examiners and administrative patent judges on the Board are "persons of scientific competence in the fields in which they work" and that their findings are "informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art." *In re Berg*, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

b. Ordinary practitioner/average expert

o "A person with ordinary skill in the art to which the invention pertains" provides a hypothetical person: who has the common general knowledge in the art to which the

o The notional person skilled in the art is considered to be an ordinary practitioner aware of the common general knowledge in the relevant art (see a. above), with average skill and ability

o "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR*, 82 USPQ2d 1385, 1397 (2007). See also the factors set forth in a. above

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invention pertains at the time of filing, and has ability to use ordinary technical means for research and development; who has ability to exercise ordinary creativity in selecting materials and changing designs; and who is able to comprehend all technical matters in the state of the art in the field to which a claimed invention pertains at the time of filing as his/her own knowledge.

(Examination Guidelines Part II.  
Chapter 2. Section 2.2(2))

but without inventive skill.  
o The knowledge and ability which can be expected of this hypothetical reference person are to be determined objectively on a case by case basis.

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c. A team of persons skilled in the art

o There may be cases where it is more appropriate to think in terms of "a group of persons" than a single person.

(Examination Guidelines Part II.  
Chapter 2. Section 2.2(2))

o There may be instances where it is more appropriate to think in terms of a group of persons rather than a single person, e.g. a research or production team in which each member has the knowledge and skill of the ordinary practitioner.

o There is no definition.

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Preliminary remarks concerning the criteria referred to in point 2. to 9.

o The examiner when looking into the question should always try to visualize the overall state of the art confronting the skilled man before contemplating the applicant's contribution, and he should seek to make a "real life" assessment of this and other relevant factors, paying proper attention to evidence from practical workers in the art.  
o The examiner should take into account all that is known concerning the background of the invention and give fair weight to relevant arguments or evidence submitted by the applicant. If, for example, an invention is shown to be of considerable

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technical value, and particularly if it provides a technical advantage which is new and surprising, and this can convincingly be related to one or more features included in the claim defining the invention, the examiner should be hesitant in pursuing an objection of lack of inventive step (see Guidelines, C-IV, 11.9.2).

- o The well-recognized secondary indicia such as those referred to in points 2. to 9. below play an important role and may be of great help in finding the proper answer to the basic question of whether or not the invention was obvious to a person skilled in the art.
- o In so far as the secondary indicia are known at the stage of examination, these criteria are taken into consideration by the examiner.
- o According to established case law, however, a mere investigation of secondary indicia is no substitute for the technically skilled assessment of inventive step. Secondary indicia are useful auxiliary elements in assessing inventive step, but they are only relevant in case of doubts, i.e., when the objective evaluation of the prior art has not provided a clear picture.
- o Finally, it should be noted that it is usually up to the applicant who wishes to rely on one or more of these criteria to produce sufficient evidence for their existence.

2. Long-felt but unsolved needs

o Whether or not a claimed invention involves an inventive

o Where the invention solves a technical problem which workers

o Objective evidence, sometimes referred to as "secondary

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step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.

(Examination Guidelines Part II.  
Chapter 2. Section 2.4(1))

in the art have been attempting to solve for a long time, or otherwise fulfils a long-felt need, this may be regarded as an indication of inventive step (Guidelines, C-IV, 11.9.4).

- o It remains to be examined carefully whether an alleged need was in effect present, whether it was felt as an urgent one, and how long it existed. In this respect, there are no general rules and the outcome will depend on the particular circumstances of each case.

considerations," may include long-felt but unsolved needs. Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel as part of the factual inquiries set forth by the Supreme Court in *Graham v. John Deere*.

- o Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 152 USPQ 602, 605 (CCPA 1967). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 168 USPQ 466 (CCPA 1971).
- o Long-felt need is analyzed as of the date the problem is identified and articulated, and there is evidence of efforts to solve that problem, not as of the date of the most pertinent prior art references. *Texas Instruments Inc. v. Int'l Trade Comm'n*, 26 USPQ2d 1018, 1029 (Fed. Cir. 1993).
- o The evidence as to long-felt but unsolved needs is usually presented as affidavits or declarations in order to rebut a holding of *prima facie*

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3. Prior art teaching away from the claim (technical prejudice)

o When there is such a description in a cited reference that precludes the reasoning the claimed invention is easily arrived at, the cited reference is not eligible for a cited invention. However, regardless of the description in a cited reference such as the difference of the problem to be solved, which prima facie precludes the reasoning, the eligibility for a cited invention shall be maintained, if the reasoning could be possible in terms of other aspects such as a close relation of technical fields or close similarity of function, work or operation, etc.

(Examination Guidelines Part II. Chapter 2. Section 2.8)

o As a general rule, there is an inventive step if the prior art leads the person skilled in the art away from the teaching of the invention. This applies in particular when the skilled person would not even consider carrying out experiments to determine whether these were alternatives to the known way of overcoming a real or alleged technical obstacle (C-IV-Annex, 4).  
o It must however be clearly shown by means of convincing facts and evidence that there was, in the relevant art, a general prejudice or misconception teaching away from, or contrary to, the invention claimed.

obviousness. The affidavits or declarations may be submitted by experts in the field though not limited to such persons.

o Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record. All rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability.

o Prior art teaching away from the invention is a secondary consideration and one of the factual inquiries that must be objectively considered by the examiner when determining obviousness.  
o A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983).  
o A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product

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for the same use." *In re Gurley*,  
31 USPQ2d 1130, 1132 (Fed. Cir.  
1994).

4. Showing the failure of  
others

o See F.2. above.

o It is one of the strongest positive sub-tests pointing to non-obviousness if it can be shown that the invention overcomes technical difficulties or solves a problem which others had been trying unsuccessfully to overcome or to solve, as this sub-test is directly related to the level of skill and knowledge of those skilled in the art which, obviously, was not sufficient to overcome the difficulty or to solve the problem. This sub-test is entirely convincing if, in addition, it can be proved that the other workers knew of the cited prior art.

o Failure of others is a secondary consideration and one of the factual inquiries that must be objectively considered by the examiner when determining obviousness.  
o See the factors identified above under long-felt need. See also MPEP 716.04.

5. Showing the invention  
lies in a very active or  
crowded art

o See F.2. above.

o Since all facts and circumstances relevant to the assessment of inventive step should be taken into consideration by the examiner, also the background of the invention and the particular situation in the technical field in question may be of importance.  
o While the mere fact that the invention lies in a very active or crowded art would not appear to be a striking argument in support of inventive step, it may be that, if the state of the art is such as to leave limited room for further advances, even a smaller step might be considered sufficient to constitute inventive step.

o The fact that an invention lies in a very active or a crowded art does not mean that smaller steps forward would therefore constitute an inventive step.  
o The criteria for determining obviousness is based upon the factual inquiries set forth by the Supreme Court in *Graham v. John Deere*. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See *KSR*, 82 USPQ2d 1385, 1396 (2007).

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6. <u>Development of brand-new technical field</u>	<ul style="list-style-type: none"><li>o See F.2. above.</li></ul>	<ul style="list-style-type: none"><li>o What has been stated before (point 5.) applies here as well.</li><li>o Where the technology involved concerns in fact a brand-new field, inventive step may be more likely to be present, in particular if there is no relevant prior art at all or if the closest prior art is fairly distant from the invention at hand.</li><li>o Applicants sometimes argue that their invention is a "pioneer" invention. It should be noted, however, that even in new technologies, pioneer inventions are rare cases and that it is mostly very difficult, at least at the stage of examination, to judge whether this is actually the case.</li></ul>	<ul style="list-style-type: none"><li>o There is no special consideration or different standards of obviousness given in evaluating the inventive step for an invention: directed to a brand-new technological field.</li><li>o The examiner evaluates the totality of the claim and makes a determination based on the factual inquiries set forth in the <i>Graham v. John Deere</i> decision.</li></ul>
7. <u>Commercial success</u>	<ul style="list-style-type: none"><li>o A commercial success or other similar facts can be taken into consideration in order to support to affirmatively infer an inventive step, insofar as the examiner finds that the fact is established by the features of a claimed invention, not by any other factors such as sales promotion technique and advertisement through an applicant's legitimate assertion or substantiation.</li></ul> <p>(Examination Guidelines Part II. Chapter 2. Section 2.8(6))</p>	<ul style="list-style-type: none"><li>o Commercial success alone is not to be regarded as indicative of inventive step, but evidence of immediate commercial success when coupled with evidence of a long-felt need is of relevance, provided the examiner is satisfied that the success derives from the technical features of the invention and not from other influences, e.g. selling techniques or advertising (Guidelines, C-IV, 11.9.4).</li></ul>	<ul style="list-style-type: none"><li>o Objective evidence, such as commercial success, relevant to the issue of obviousness must be evaluated by Office personnel. The objective evidence of nonobviousness must be commensurate in scope with the claims.</li><li>o Evidence of the commercial success must establish a nexus between the claim and the success.<ul style="list-style-type: none"><li>o In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or</li></ul></li></ul>

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			advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention. <i>In re Mageli</i> , 176 USPQ 305 (CCPA 1973). See MPEP 716.03 to 716.03(b).
8. <u>Complexity of the technology</u>	o See F.2. above.	<ul style="list-style-type: none"> <li>o The peculiar situation of the technical field in question will always play a role in determining the basic question of whether an invention would have been obvious to a person skilled in the art.</li> <li>o The fact that the relevant art is a complex technology may also have some impact. However, the concept of "complexity" is too vague and indefinite to make it a proper sub-test for inventive step.</li> </ul>	<ul style="list-style-type: none"> <li>o There is no special consideration or different standards of obviousness given in evaluating the inventive step for an invention because of the technical field.</li> <li>o The examiner evaluates the totality of the claim and makes a determination based on the factual inquires set forth in the <i>Graham v. John Deere</i> decision.</li> </ul>
9. <u>Other criteria</u>	o No other comments.	<ul style="list-style-type: none"> <li>o Unexpected technical advance or advantageous effect is probably the most important criterion for non-obviousness, and not only in chemical cases.</li> <li>o An inventive step may then be found for:                             <ul style="list-style-type: none"> <li>- inventions involving the use of known measures in a non-obvious way or known working methods or means used for a different purpose and involving a new, surprising effect or overcoming technical difficulties not resolvable by routine techniques;</li> <li>- combination of features mutually supporting each other to such an extent that a new technical result is achieved;</li> <li>- special selection in a process of particular operating conditions</li> </ul> </li> </ul>	o No other comments.

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within a known range if the selection produces unexpected effects in the operation of the process or for the resulting product.

- o In frequently studied fields of commercial importance, the EPO Boards of Appeal have also considered, on a case-by-case basis:
    - the age of the document, if the period of time between the date of publication of the prior art document and the date of filing of the patent application was an indication of a long-felt need;
    - the simplicity of the claimed solution in fields where simple solutions without loss of quality or efficiency were deemed impossible and/or there was no hint in the prior art towards such solution.
  - o However, it should again be kept in mind that in "one-way street" situations, it would always have been obvious for a skilled person to arrive at something falling within the terms of the claim. A mere "bonus effect" does not of itself confer inventiveness to a claim.
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II. Special consideration  
applicable to chemical practice

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A. Criteria used to determine  
the inventive step based  
upon

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1. a. Unexpected or  
superior properties  
of a chemical

- o Where an invention with a generic concept is expressed in a cited reference, an invention selected from the generic concept is called "selection invention", if it is novel over the generic invention and pertains to a technical field in which an effect of a product is difficult to understand from its structure. Where an invention is expressed as alternatives either in form or de facto in a cited reference, an invention selected from a group of inventions each of which is identified by supposing that each of the alternatives is a matter to define each of such inventions is also called "selection invention", if it is novel over the alternatives and pertains to a technical field in which an effect of a product is difficult to understand from its structure. Thus, an invention can be a selection invention, if it is not an invention described in a publication.
- o A selection invention involves an inventive step, when it generates an advantageous effect which is qualitatively different or qualitatively the same but quantitatively prominent in comparison with that of an invention with a generic concept in a cited invention, neither of
- o Inventive step in chemical inventions is certainly more often based on an unexpected effect than it is in any other field of technology, because the level of predictability is much lower for chemicals than it is for inventive features in other fields for instance in the mechanical field.
- o The EPO practice is to accept an unexpected new technical effect (result, property, use) as evidence in favor of inventive step.
- o An unexpected effect or use may be an entirely new effect or use, or a substantial improvement of those already known. If the claimed compound is structurally close to already known compounds, a new and unexpected effect or use will always be required for inventiveness.
- o In practice, unexpected effects which are presented by applicants in support of inventive step are either new or superior effects.
- o A substance having a similar chemical structure to a known chemical would be considered nonobvious where the substance contains unexpected or superior properties not in fact possessed by the known chemical. This is because "[a] chemical composition and its properties are inseparable." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Furthermore, evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to support a determination that the claimed invention would not have been obvious. *In re Chupp*, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

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which is foreseen by a person skilled in the art from the state of the art nor disclosed in a cited reference.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3) )

b. Determination of inventive step between chemical substance of similar structure

o Whether or not a claimed invention involves an inventive step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.

(Examination Guidelines Part II.  
Chapter 2. Section 2.4(1))

o If the compounds of the prior art were described as having a different effect, unrelated to the one exhibited by the new compounds, or no effect at all, inventive step will be acknowledged by the examiner provided he is satisfied that the effect of the new compounds is in effect an unexpected one in view of what the prior art teaches.

o The examiner is not entitled to simply argue that a property is inherent to the chemical nature of a compound. Only in extremely rare cases may the mere disclosure of a compound be said to teach at the same time the man skilled in the art that this compound will evidently exhibit a certain activity. Such an argument would have to be based on sound evidence provided by the examiner.

o Inventive step of novel chemical compounds is based in most cases on an unexpected property or activity. This unexpected result may be a different effect or a difference in degree, i.e. a superior effect, when compared with the prior art compounds.

o From the standpoint of U.S. patent law, a compound and all its properties are inseparable. Patentability of a chemical compound cannot be determined based on structure alone. The examiner must consider the structure of the compound and its properties in determining obviousness. See MPEP 2144.08 and 2144.09.

o Level of skill in the art and secondary considerations such as commercial success or unexpected results must also be considered by the examiner in the determination of obviousness.

o Thus, a *prima facie* case of obviousness based on structural similarity is rebuttable by evidence that the claimed compound possessed new and unexpected properties not possessed by the structurally similar prior art compound. *In re Papesch*, 137 USPQ 43 (CCPA 1963) o The court in *In re Soni*, 34 USPQ2d 1688, 1684 stated  
"Mere improvement in properties does not always suffice to show unexpected results. In our view, however, when an applicant demonstrates *substantially* improved results, . . . , and *states* that the results were *unexpected*, this should suffice to establish unexpected results

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*in the absence of evidence to the contrary."*

- o The discovery of latent properties does not render the claimed compound novel: "Our cases have consistently held that a reference may anticipate even when the relevant properties of the thing disclosed were not appreciated at the time . . . The general principle that a newly-discovered property of the prior art cannot support a patent on that same art is not avoided if the patentee explicitly claims that property." *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 80 USPQ2d 1860, 1863-1864 (Fed. Cir. 2006).

2. Evidence required to evaluate therapeutic properties

- o As for working examples supporting the medicinal use, a description of the result of the pharmacological test is usually required.
- o Since the result of the pharmacological test is to confirm the pharmacological effect of the claimed medicinal invention, all of the followings should be made sufficiently clear, in principle; (i) which compound is, (ii) applied to what sort of the pharmacological test system, (iii) what sort of result is obtained, and (iv) what sort of relationship the pharmacological test system has with the medicinal use of the claimed medicinal invention.
- o Public health and safety matters are usually not considered in the EPO. In very exceptional cases, however, an objection may be raised under Article 53 (a) EPC (inventions, the commercial exploitation of which would be contrary to "ordre public" or morality).
- o If the invention is for compounds said to exhibit a "new therapeutic effect", the EPO would require no special evidence in support of this new effect.
- o If the invention is for compounds said to exhibit an unexpectedly improved therapeutic effect, evidence would be required in comparison with compounds of the state of the art known to have this same effect.
- o In considering matters relating to the adequacy of disclosure of utility in drug cases:
  - (1) The same basic principles of patent law which apply in the field of chemical arts (and all other arts as well) shall be applicable to drugs, and
  - (2) The USPTO shall confine its examination of disclosure of utility to the application of patent law principles, recognizing that other agencies of the government have been assigned the responsibility of assuring conformance to the standards established by statute for the advertisement, use, sale or distribution of drugs.

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(1) Relationship between the medicinal use and the working mechanism

Even if the medicinal use of the claimed medicinal invention differs from the medicinal use of the cited invention, when the relevance of the working mechanism between both has been derived from the publicly known art or common general knowledge at the time of filing, the inventive step of the medicinal invention of the present patent application is usually denied, unless otherwise there is another ground for inferring inventive step such as advantageous effect or the like.

(2) Conversion of a medicine for animals other than human beings to a medicine for human beings

A claimed medicinal invention, derived by merely converting one compound or one group of compounds of a cited invention used for the same or a similar kind of diseases of animals other than human beings into a medicine for human beings, usually does not involve an inventive step even if there is no suggestion in the contents of the cited invention about the pertinent conversion, unless otherwise there is another ground for inferring inventive step such as advantageous effect or the like..

The situation is the same with the conversion of a medicine for human beings to into a medicine for animals other than human

- o Comparative tests would be considered as being sufficient if they were conducted on animals or in vitro in place of clinical tests.
- o Toxicity would also not be questioned, except of course in cases where a reduced toxicity would in itself be the unexpected effect of the invention.

- o Evidence submitted to demonstrate utility is relevant in determining whether the claimed invention has utility when there is a reasonable correlation between the asserted utility and such evidence. See MPEP 2107.02. For example, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980).
- o There is no requirement for the results of any toxicity tests.
- o While an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for USPTO personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See MPEP 2107.03.

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beings.

(3) Medicine formulated by combining two or more medicinal components

In order to solve a problem well known to a person skilled in the art such as an increase in a medicinal effect, or the reduction of a side effect, optimization of the combination of two or more medicinal components is among exercise of ordinary creativity of a person skilled in the art. When the difference between the claimed medicinal invention and the cited invention falls only on these points, ordinarily, the inventive step of the claimed medicinal invention is denied.

On the other hand, in the claimed medicinal invention defined by a combination of two or more medicinal components, when the combination of the components is novel and a remarkable effect is performed by the combination of two or more compounds or groups of compounds, the claimed medicinal invention can involve an inventive step.

(Examination Guidelines Part VII. Chapter 3. "Medicinal Inventions" Section 2.3.1.1)

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3. Intermediates

o There are no criteria used to determine the inventive step based upon intermediates.

o The EPO grants claims only for chemical intermediates which can be isolated.  
o In the EPO, the expression "intermediate products" means compounds which do not necessarily have any useful

o For unstable and transitory chemical intermediates, the enablement requirement does not require that the applicant teach how to make the product in stable, permanent, or isolatable form. *In re Breslow*, 205 USPQ

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direct application but which serve as starting or intermediate substances for producing other subsequent chemical substances (end products) in an inventive process.

- o Two categories of intermediates have to be considered here:
  - (i) intermediates used in an inventive process. In such cases, the non-obviousness of the intermediate may (but will not necessarily) be derived from its contribution to the inventive process;
  - (ii) intermediates used in a standard process or in an analogy process for the preparation of a patentable "subsequent product". In such cases, the intermediate must produce a "structural contribution" to the subsequent product, and said structural contribution must be at least one of the features that differentiate the subsequent product from those already known in the prior art.

221, 226 (CCPA 1980). However, chemical intermediates must have a specifically identified substantial utility.

- o The patentability of a chemical intermediate may be established by unexpected properties of an end product "when one of ordinary skill in the art would reasonably ascribe to a claimed intermediate the contributing cause for such an unexpectedly superior activity or property." *In re Magerlein*, 202 USPQ 473, 479 (CCPA 1979).

4. Inventive step of invention defined by parameters (e.g. numerical formula)

- o Where a claim includes statements defining a product by its function or characteristic, etc. and it falls under either the following or , there may be cases where it is difficult to compare the claimed invention with a cited invention. In the above circumstances, if the examiner has a reason to suspect that the claimed product would be prima facie similar to

- o A chemical product may be defined in a claim by its formula, as a product of a process or, in exceptional cases, by its parameters. However, the characterization of a product mainly by its parameters should only be allowed in those cases where the invention cannot be adequately defined in any other way.
- o In this respect, parameters are characteristic values, which may

- o It is inappropriate to dissect claims into old and new elements and then to ignore the old elements in the analysis. This is the same for process claims that contain numerical formulas in that the process steps cannot be separated from the formulas. The claim must be considered as a whole.

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the product of the cited invention and that the claimed invention would prima facie involve no inventive step without making a strict comparison of the claimed product with the product of the cited invention, the examiner may send the notice of reasons for refusal under Article 29(2).

Then an applicant may argue or clarify by putting forth a written argument or a certificate of experimental results, etc. against the notice of reasons for refusal.

The reason for refusal is to be dissolved if the applicant's argument succeeds in changing the examiner's evaluation at least to the extent that it is unclear that the claimed product is prima facie similar to the product of the cited invention and that the claimed invention would prima facie involve no inventive step.

Where the applicant's argument, which is, for example, abstract or general, does not change the examiner's evaluation to that extent, the examiner may make a decision of refusal under Article 29(2).

A case where the function or characteristic, etc. is neither standard, commonly used by a person skilled in the art in the relevant technical field nor comprehensible of its relation to a commonly used function or characteristic, etc. to a person skilled in the art if the function or characteristic is not commonly used; or

A case where plural of functions

be values of directly measurable properties (e.g., the melting point of a substance) that can be clearly and reliably determined by objective procedures well-known in the art", or they may be defined in the form of formulae.

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or characteristics, etc. each of which is either standard, commonly used by a person skilled in the art in the relevant technical field or comprehensible of its relation to a commonly used function or characteristic, etc. to a person skilled in the art if the function or characteristic is not commonly used, are combined in a claim so that the claim statements as a whole fall under .

(Examination Guidelines Part II.  
Chapter 2. Section 2.6(1))

5. Other criteria

a. Characteristic of manufacturing method of a chemical substance and an inventive step as an invention of chemical substance

o If a claim is one with statements defining a product by its manufacturing process, there may be cases where it is difficult to determine what the product per se structurally is. In such circumstances, if the examiner has a reason to suspect that the claimed product would be prima facie identical with the product of the cited invention and that the claimed invention would prima facie involve no inventive step without making a strict comparison of the claimed product with the product of the cited invention, the examiner may send the notice of reasons for refusal under Article 29(2).

(Examination Guidelines Part II.  
Chapter 2. Section 2.7(1))

o A claim for such a product is considered as a claim for the product per se.  
o Such a product must comply with the requirements for novelty and inventive step independently of its process of manufacture.

o A claim for a product defined by its method of manufacture is considered to be a claim for the product, per se. The patentability of the product, not recited process steps, must be evaluated in these types of claims.

B. Criteria to evaluate

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compositions or structures

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1. Chemical product patentable per se

- o Whether or not a claimed invention involves an inventive step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.

(Examination Guidelines Part II.  
Chapter 2. Section 2.4(1))

- o A chemical product may be considered as being patentable, i.e. inventive, independently of any use, effect or property it might have, if its structure is non-obvious. However, there is a tendency to expect indication of a useful effect.

- o Chemical products are patentable, *per se*, as compositions of matter, if they satisfy the utility, written description, enablement, novelty and nonobviousness requirements of the patent statute.
- o

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2. Structural obviousness in chemical cases

- o Reasoning is attempted by confirming and taking into consideration an advantageous effect, if any, of a claimed invention compared to cited inventions. It should be noted that, regardless of advantageous effects, inventive step may be denied by the uncontested reasoning that a person skilled in the art could have easily arrived at a claimed invention.
- o However, when the advantageous effect compared to the cited invention so remarkable that it cannot be foreseen by a person skilled in the art from the state of the art, there may be cases where its inventive step is affirmed.  
For example, even though a reasoning seems to be possible that a person skilled in the art

- o Mere structural similarity is not a ground for denying inventive step. On the other hand, inventive step will have to be based on an unexpected effect.
- o If the new compounds exhibit an unexpected use or effect which was not known for close compounds of the prior art, the new ones will be considered as being inventive.
- o If the new use or effect is only an improvement in a result of the same kind as is known for the known compounds, it must be first established whether such an improvement would have been expected by the person skilled in the art from common general knowledge or any specific prior art disclosure. If it is the case, the structural "distance" between the new compounds and the closest compounds in the prior

- o The determination of obviousness with regard to a chemical substance is based not only on the chemical structure but also on its properties.
- o A chemical substance that is *prima facie* structurally obvious but produces an unexpectedly different property or result compared to the closest prior art compound would be considered nonobvious.
- o A chemical substance that is *prima facie* structurally obvious in view of the prior art but produces a superior result in the same property would be considered nonobvious. That is, there is a significant difference in degree in the same property amounting to unexpected superiority.

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could have easily arrived at a claimed invention because of the close similarity between the matters defining a cited invention and the ones defining a claimed invention or because of a combination of plural cited inventions, the inventive step should be positively inferred if a claimed invention has an advantageous effect, qualitatively different or qualitatively the same but quantitatively prominent in comparison with those of cited inventions, and if the advantageous effect cannot be foreseen by a person skilled in the art from the state of the art.

Particularly, in the case of an invention in a technical field in which an effect of a product is difficult to predict from its structure, the advantageous effect compared to the cited invention is an important fact to positively infer its inventive step.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3) )

art will have to be considered, taking into account the predictability of the effect in that particular field (structure/activity relationship).

3. Purer form of known product

o See II.B.1. above.

o A mere increase in purity is not sufficient to establish non-obviousness for a known compound.  
o Admitted, novelty of the purer form has been acknowledged, increase in purity will still have to exhibit some unexpected property or effect, or a significant contribution to the claimed invention.

o The purified form of a known product would have been obvious unless the recovered product has an unexpected effect or utility not shared by the prior art. See MPEP 2144.04.

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4. <u>Novel physical forms; e.g. new crystalline structure</u>	<ul style="list-style-type: none"> <li>o See II.B.1. above.</li> </ul>	<ul style="list-style-type: none"> <li>o Admitted, novelty of the new physical form has been established, such form may be inventive as such (see II.B.1 above), or because it provides some unexpected and/or surprising effect or property which was not known for other physical forms already disclosed in the prior art.</li> </ul>	<ul style="list-style-type: none"> <li>o A novel physical form for a chemical substance e.g. new crystalline structure, would not constitute an inventive step unless there was shown an unexpected utility or effect from the known substance.</li> </ul>
5. <u>Products of nature</u>	<ul style="list-style-type: none"> <li>o One of the requirements for a statutory invention is to be a "creation", and thus, mere discoveries, such as discoveries of natural things like an ore or natural phenomena, for which an inventor does not consciously create any technical idea, are not considered to be a statutory invention.                       However, if things in nature such as chemical substances or microorganisms have been isolated artificially from their surroundings, then those are creations and considered to be a statutory invention.                       (Examination Guidelines Part II. Chapter 1. Section 1.1(2))</li> </ul>	<ul style="list-style-type: none"> <li>o A substance freely occurring in nature is a mere discovery excluded from patentability under Article 52 (2) (a) EPC. However, if a substance found in nature can be shown to produce a technical effect (i.e., an antibiotic effect), it may be patentable.</li> <li>o If, on the other hand, a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process may be patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and it is "new" in the absolute sense of having no previous recognized existence, then the substance per se may be patentable.</li> </ul>	<ul style="list-style-type: none"> <li>o A patent cannot be obtained on a product in the form it exists in nature even though it is obtained from sources and by processes not previously utilized. However, the isolated substance would have been considered nonobvious where the isolated purer chemical substance has an unexpected effect or utility not shared by the prior art substance or the product as in its natural form.</li> </ul>
6. <u>Effects of components of a mixture</u>	<ul style="list-style-type: none"> <li>o If matters defining an invention are not linked each other functionally or operationally and the invention is a combination of each matter (mere juxtaposition of features), the invention is deemed as a mere exercise of ordinary creativity of a person skilled in the art, unless otherwise there is another</li> </ul>	<ul style="list-style-type: none"> <li>o If the mixture has exhibited an unexpected effect in comparison with what was to be expected from the elements of the mixture, such a mixture will be patentable as an inventive combination.</li> <li>o Combinations claimed in the form of "kits of parts" may be considered as inventive if there is a functional unity through a</li> </ul>	<ul style="list-style-type: none"> <li>o There is no inventive step from the intermixing of two or more ingredients where the resultant mixture only contains the expected effects from each ingredient. See <i>KSR International Co. v. Teleflex Inc.</i>, 82 USPQ2d 1385, 1395-97 (2007)(discussing obviousness of combining prior art elements</li> </ul>

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	<p>ground for inferring inventive step.</p> <p>(Examination Guidelines Part II. Chapter 2. Section 2.5(1) )</p>	<p>purpose-directed application, and the combination exhibits an unexpected and/or surprising effect.</p>	<p>according to known methods to yield predictable results).</p>
<p>7. <u>Various chemical forms of a compound; e.g. isomers</u></p>	<p>o See II.B.1. above.</p>	<p>o The first requirement to be satisfied for possible various forms of one and the same compound is novelty. Once novelty is established, an unknown isomer of a known compound exhibiting unexpected properties may be patentable.</p> <p>o Even in the case where a racemic mixture, which is a mixture of equal parts of a dextro- and a levo-isomer, is known, one of the optically active constituents would be considered as inventive if it is novel and exhibits an unexpected effect when compared to the racemic mixture.</p>	<p>o A new and useful compound which is isomeric with a compound of the prior art might not contain an inventive step unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. However, isomers that have the same empirical formula but different structures are not necessarily considered equivalent by chemists skilled in the art and therefore are not necessarily suggestive of each other. <i>Ex parte Mowry</i>, 91 USPQ 219 (Bd. App. 1950).” MPEP 22144.09.</p>
<p>C. 1. <u>Criteria for chemical processes; e.g. process producing known chemical product, old process using new starting materials, etc.</u></p>	<p>o Where an invention of a product per se involves an inventive step, inventions of a process of producing the product or of a use of the product involves an inventive step in principle.</p> <p>(Examination Guidelines Part II. Chapter 2. Section 2.8(5))</p>	<p>o Basically, there are three types of processes:</p> <p>(1) Processes based on a new chemical reaction. If the application is for an entirely novel chemical reaction type inventive step will be recognized without difficulty.</p> <p>(2) Processes based on a known reaction for the production of a patentable product. In such cases, the process may be based on either:</p> <p>* starting materials which are different from but of a similar constitution to the compounds previously used in the known processes, and which are reacted together following</p>	<p>o Analogous process which produces Expected Result:</p> <p>There would be prima facie obviousness in the process which merely used different starting materials, known or unknown, and produced a product expected therefrom.</p> <p>o Processes which produce unexpected product or result: A process would not have been considered obvious when that process produced an unexpected result which would not be apparent from the reactants employed even though the product would inherently result therefrom. The unexpected result could be an unexpected increase</p>

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the same procedures, to give, as expected, new compounds of similar constitution to the products obtained by the known processes, or

- \* starting materials which are identical to those used in the known processes and employed following a similar procedure, to produce, as expected new compounds of similar constitution to the products obtained by the known processes.

In both cases, non-obviousness will be acknowledged if the chemical compound obtained is novel and inventive.

- (3) Processes based on a known reaction and producing a known chemical product. Non-obviousness assessment will be based on features of the process itself and will depend on whether, due to special reaction conditions, an unexpected effect is obtained.

in yield when employing less reactant.

- o The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. See MPEP 2112.02. A process would have been nonobvious where the result of the process and the particular use of the material was not suggested by the prior art.

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<p>2. <u>Need for processes, including analogy process, or methods of use to be separately considered for inventive step when leading to or involving patentable products.</u></p>	<p>o See II.C.1. above.</p>	<p>o Inventive step for an analogy process is accepted automatically provided that the process leads to a patentable product.</p> <p>o In the case of a process based on a new chemical reaction, the process may exhibit its own inventive step, independently of the resulting product.</p> <p>o In both cases however, the examiner need not in fact examine the inventive step of the process, if it leads to a patentable end product.</p> <p>o The same reasoning applies for uses of a patentable product, which could or could not exhibit their own non-obviousness. As soon as the product is considered as being inventive, inventive step of the use need not be considered separately.</p>	<p>o <i>In re Ochiai</i>, 37 USPQ2d 1127 (Fed. Cir. 1995) and <i>In re Brouwer</i>, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. Determining whether an invention involves an inventive step requires a highly fact-dependent analysis which takes the claimed subject matter as a whole and compares it to the prior art. "A process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious." <i>TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc.</i>, 67 USPQ2d 1511, 1514 (Fed. Cir. 2003). See also MPEP 2116.01.</p>
<hr/>			
<p>D. <u>Other considerations to determine the inventive step in chemical practice</u></p>			
<p>1. <u>Secondary tests (subtests) of non-obviousness</u></p>	<p>o See from I.F.2. to I.F.8. above.</p> <p>o There is no other "Secondary tests".</p>	<p>o The secondary tests which apply in the chemical field are those listed in Part I.F.2 to 8. above.</p>	<p>o There are no secondary or subtests employed in determining nonobviousness in the chemical practice. The examiner makes the same factual inquiries as would an examiner in the mechanical practice.</p>

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2. Extent to which comparative tests are required

- o Even though a reasoning seems to be possible that a person skilled in the art could have easily arrived at a claimed invention because of the close similarity between the matters defining a cited invention and the ones defining a claimed invention or because of a combination of plural cited inventions, the inventive step should be positively inferred if a claimed invention has an advantageous effect, qualitatively different or qualitatively the same but quantitatively prominent in comparison with those of cited inventions, and if the advantageous effect cannot be foreseen by a person skilled in the art from the state of the art.

Particularly, in the case of an invention in a technical field in which an effect of a product is difficult to predict from its structure, the advantageous effect compared to the cited invention is an important fact to positively infer its inventive step.

(Examination Guidelines Part II.  
Chapter 2. Section 2.5(3) )

- o Where advantageous effects compared to cited inventions are described in a specification, or where advantageous effects are not explicitly described but can be inferred from the statements in the specification or the drawings by a person skilled in the art, the effects asserted or verified (e.g., experimental

- o Comparative tests may be submitted as evidence of an unexpected or improved effect. It is up to the applicant to decide on the kind of evidence he wishes to submit in support of the nonobviousness of his patent application.

\* Comparative tests should only be called for when absolutely necessary.

\* If the application is for new compounds said to exhibit an unexpected effect on which the inventive step is based, and no effect or a different (unrelated) effect has been mentioned in the prior art for the structurally closely related known compounds, no comparative tests or any other kind of evidence will be necessary in order to establish an inventive step of the new compounds.

\* If the application is for new compounds said to exhibit an unexpected effect on which the inventive step is based, and the same effect or a related effect has been mentioned in the prior art for structurally closely related known compounds, comparative tests will be necessary if the applicant is unable or unwilling to state any other evidence that would render the existence of an inventive step plausible.

- o \* Whenever a comparative test is made, the comparison must be with the technically closest prior art.\* The number of comparative steps and their distribution on the scope of

- o There is no requirement to submit comparative test results.
- o Comparative tests are usually submitted as rebuttal evidence to show unexpected results once the USPTO has established a prima facie case of obviousness.
- o The comparative tests must be between the claimed invention and the closest prior art.

COMPARISON OF JPO, EPO & USPTO PATENT PRACTICE

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	<p>results) in a written argument, etc. should be considered. However, the effects asserted in the written argument, which are not described in the specification and that a person skilled in the art couldn't deduce from the description of the specification or the drawings, should not be taken into consideration.</p>	<p>the claimed invention is to be decided on a case by case basis.</p> <ul style="list-style-type: none"><li>o * The criteria above have been mainly developed for chemical compounds but apply mutatis mutandis to chemical processes.</li></ul>	
	<p>(Examination Guidelines Part II. Chapter 2. Section 2.5(3) )</p>		
3. <u>Others</u>	o No other comments.	o No other comments.	o No other comments.

COMPARATIVE ANALYSIS

## I. Determining inventive step

### A. Judicial, legislative or administrative criteria or guidelines for determining inventive step

#### 1. Legislation

Relevant provisions in laws and implementing regulations are reproduced in Appendix I-1 (JPO), I-2 (EPO), I-3 (USPTO).

#### 2. Guidelines

Guidelines for examination, Examination Guidelines, etc. are reproduced in Appendix II-1 (JPO), II-2 (EPO), II-3 (USPTO).

#### 3. Background and purpose of the provisions relating to inventive step

The import of all three Offices is identical, though each differs in expression. That means, in essence, the purpose of the provisions for inventive step is "to exclude from granting exclusive rights (Patent rights) to inventions that could be made easily by a person skilled in the art, recognizing that to do so would hinder development of technology."

### B. Claim interpretation criteria

The practices of all three Offices agree in points that "the claim(s)" is considered to consist of independent and dependent claims, and that inventive step is determined for each claim.

In the JPO, the scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent. In such case, an invention specified by a statement in one claim may be the same invention specified by a statement in another claim. (Article 36(5) of the Patent Act)

There is no difference among the three Offices in requiring description of the extent of protection sought.

#### 1. Application of prior art to a claim with a preamble stating features necessary for definition of

claimed subject matter followed by a characterizing portion stating those technical features to be protected

The practices of the EPO and the USPTO coincide in that Jepson type claims, as in the case of improvement, are encouraged but not compulsory, and that the matter stated in the preamble of the claim is taken into consideration when determining inventive step.

The statement of prior art mentioned in the preamble of the claim can be used as a basis of refusal in the EPO and the USPTO, but generally not in the JPO.

## 2. Determination of claimed scope and content

All three Offices follow the same practice in interpreting the claims by taking into account the specification and drawings, and assessing inventive step on the basis of the claims.

In the USPTO, during examination, the words of the claim are given the broadest reasonable interpretation in light of the specification.

In the JPO, the determining of a claimed invention should be made on the basis of the statements of the claim. Matters stated in the claim defining the claimed invention should be construed in the light of the description in the specification, the drawings and the common general knowledge as of the filing. (Examination Guidelines Part II. Chapter 2. "1.Novelty" Section 1.5.1)

Similar rules for claim construction (claims to be read in the light of the description and the drawings) apply in the EPO.

## 3. Dependent claim interpretation

All three Offices interpret the dependent claims as including all limitations in the cited claim.

The EPO states that if an independent claim is new and non-obvious, there will, in almost all of the cases, be no need to investigate whether any claim dependent thereon involves an inventive step. The EPO also mentions that a claim referring to another claim does not necessarily imply that the claim containing the reference is in fact a dependent one. A claim may in effect also contain a reference to another claim even if it is not a dependent claim. In such cases, the examiner will carefully consider the extent to which the claim containing the reference necessarily involves the features of

the claim referred to and the extent to which it does not.

In the USPTO, effective November 1, 2007, the rules of practice for the examination of claims in an application (37 CFR 1.75) has been revised to provide that if the number of independent claims is greater than 5 or the number of total claims is greater than 25, the Office will require the applicant to submit an examination support document (ESD) complying with 37 CFR 1.265 covering all of the claims in the application. If applicant chooses not to file an ESD, the application must be amended to contain no more than 5 independent claims and no more than 25 total claims. [Note: In view of the preliminary injunction issued by the U.S. District Court for the Eastern District of VA on Oct. 31, 2007, the changes to the rules of practice in the claims and continuation final rules did not go into effect on Nov. 1, 2007.]

In the JPO, the independent form claims and dependent form claims differ only in the form of description, and are treated in the same manner. (Examination Guidelines Part I. Chapter 1. "Description Requirements of the Specification" Section 2.2.4)

C. Basic approach applied in assessing inventive step  
e.g. test for non-obviousness, avoidance of ex post facto reasoning, and considering what the skilled man would have done starting from a given problem

The approach applied by three Offices coincides in that the assessment of inventive step is made by comparing the invention with prior art and recognizing the difference between them.

However, while the determination of inventive step is based on the "time the application was filed (or the date of priority, if priority is claimed)" in the JPO and the EPO, where the first-to-file principle is adopted, it is based on the "time the invention was made" in the USPTO, where the first-to-invent principle is adopted.

In the JPO practice, after determining what is described in a claimed invention and one or more cited inventions, one cited invention most suitable for the reasoning is selected. And comparison of the claimed invention with a cited invention is made, and the identicalness and the difference in matters defining the inventions are clarified. Then, the reasoning for lacking an inventive step of the claimed invention is attempted on the basis of contents of the selected invention above, other cited inventions (including well-known or commonly used art) and the common general knowledge. The reasoning can be made from various and extensive aspects. For example, the examiner evaluates whether the claimed invention falls under a selection of an optimal material, a workshop modification

of design, a mere juxtaposition of features on the basis of a cited inventions, or whether the contents of cited inventions disclose a cause or a motivation for a person skilled in the art to arrive at the claimed invention.

If advantageous effects of the claimed invention over a cited invention can be clearly found in the description in the specification, etc., it is taken into consideration as facts to support to affirmatively infer the involvement of an inventive step.

(Examination Guidelines Part II. Chapter 2. Section 2.4, 2.5)

In EPO practice, the approach generally applied (the so-called problem-solution approach) may be summarized as follows: 1) comparing the claimed invention with the closest prior art in order to determine the differences, 2) establishing objectively, in the light of that closest prior art, the problem that is actually solved by the invention, and 3) determining whether a person skilled in the art, starting from the closest prior art and the problem so established, would arrive at the invention claimed on the basis of the relevant prior art and/or common general knowledge.

In the USPTO, in determining obviousness, the factual inquiries set forth by the U.S. Supreme Court in *Graham v. John Deere* apply. The factual inquiries are: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; and (3) resolving the level of ordinary skill in the art while taking into account secondary consideration. The Supreme Court in *KSR International Co. v. Teleflex Inc.* (*KSR*) noted that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Exemplary rationales that may support a conclusion of obviousness include:

- (1) Combining prior art elements according to known methods to yield predictable results;
- (2) Simple substitution of one known element for another to obtain predictable results;
- (3) Use of known technique to improve similar devices (methods, or products) in the same way;
- (4) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (5) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (6) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (7) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

The list of rationales provided is not intended to be an all-inclusive list. Other rationales to

support a conclusion of obviousness may be relied upon by Office personnel.

D. Criteria for determining the ability to apply prior art from non-analogous technical fields

The practices of three Offices coincide in that the application of prior arts is not limited in the technical field to which the invention pertains.

In the EPO, prior art in neighboring fields might be considered as well. However, prior art in remote technical fields will not be considered.

E. Criteria for determining the differences between the prior art and the claims

1. Combinations of prior art

a. Requirements, if any, of a teaching or suggestion to combine features

There is no difference among the three Offices on the following two points:

- (1) The examiner will reject an invention as not having an inventive step, if the invention is a mere juxtaposition of publicly known arts and not producing any new effect other than the arithmetic sum of the combined features.
- (2) The examiner must logically give reasons as to why a person skilled in the art would have combined the features cited in the documents.

The U.S. Supreme Court in *KSR* recognized that the teaching-suggestion-motivation (TSM) rationale was one of a number of valid rationales that could be used to determine obviousness. Other rationales identified in C. above may support a conclusion of obviousness.

b. Restrictions, if any, on the ability to modify a prior art teaching; e.g. the number of prior art teachings that can be combined

The practices of three Offices coincide in that there is no specific limitation on the number of prior arts that can be combined.

The EPO, however, has pointed out that the higher the number of teachings which are being combined, the more likely it is that prohibited ex post facto analysis or lack of proper

reasoning is involved.

2. Problem of common general knowledge

i.e. the question as to whether the examiner, if he is reasonably certain that a given feature is common general knowledge but cannot prove it (because there is no supporting document), is entitled to refuse a claim

a. On the basis of that knowledge alone

The EPO mentions that, in exceptional cases, the examiner may rely on his/her personal knowledge in the relevant technical field to refuse a claim without producing a concrete citation when no such citation exists.

However, if the applicant objects to the refusal and the examiner is unable to produce documentary evidence, he should maintain the objection only if he is certain of his position.

In the JPO, since well-known or commonly used art is important material constituting the state of the art which can be a ground for a notice of reasons for refusal, well-known or commonly used art should be accompanied with an exemplary document insofar as possible except when it is so well-known that any evidential document seems unnecessary, regardless of whether it is used as a basis to determine the cited invention or to determine the knowledge (the state of the art including the common general knowledge) or the ability (the ability to use ordinary technical means for research and development or the ordinary creativity) of a person skilled in the art if an examiner refers to well-known or commonly used art. (Examination Guidelines Part II. Chapter 2. Section 2.8(2))

In the USPTO, in certain circumstances where appropriate, an examiner may take official notice of facts not in the record or rely on "common knowledge" in making a rejection, however, such rejections should be judiciously applied. In addition, it is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection is based. See *In re Zurko*, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001).

When the applicant objects to the refusal, under three Offices' practices, the examiner should cite a reference in support of his/her position.

The USPTO's report states that failure of the applicant to traverse or adequately traverse the examiner's finding of "common knowledge" establishes the examiner's finding as admitted prior art. In such cases the examiner may make a final rejection on the basis of common general

knowledge without documentary proof to support the rejection.

b. On the basis of that knowledge combined with one or more published pieces of prior art

The same applies as for a. above.

The USPTO also notes that if the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).

3. Criteria for evaluating differences between the prior art and the invention in regard to:

a. Temperature or other ranges

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step if the invention constitutes a change in temperature or other ranges of prior art which could have easily been made by a person skilled in the art and which does not produce but a normally expected effect/result.
- (2) All Offices recognize inventive step when the new feature produces an unexpected effect/result and the choice of the new feature enables the conventional technical expectation to be surpassed.

b. Shapes or configurations

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step if the invention constitutes a change in shape or configuration of prior art which could have easily been made by a person skilled in the art and which does not produce but a normally expected effect/result.
- (2) All three Offices recognize inventive step when the new feature produces an unexpected effect/result and the choice of the new feature enables the conventional technical expectancy to be surpassed.

c. Materials or parts

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step if the invention constitutes a partial change or limitation of materials or parts of prior art which could have easily been made by a person skilled in the art and which does not produce but a normally expected effect/result.
- (2) All three Offices recognize inventive step when the new feature produces an unexpected effect/result and the choice of the new feature enables the conventional technical expectancy to be surpassed.

d. Sizes, ratios or amounts

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step if the invention constitutes a change or a numerical limitation of sizes, ratios or amounts of prior art which could have easily been made by a person skilled in the art and which does not produce but a normally expected effect/result.
- (2) All three Offices recognize inventive step when the new feature produces an unexpected effect/result and the choice of the new feature enables the conventional technical expectancy to be surpassed.

e. Reversed elements or parts

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step for an invention obtained by reversing elements or parts of prior art for elements or parts of another prior art, which could have easily been made by a person skilled in the art and which does not produce but a normally expected effect/result.
- (2) All three Offices recognize inventive step when the new feature produces an unexpected effect/result and the choice of the new feature enables the conventional technical

expectancy to be surpassed.

f. Omitted elements or parts

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step if the invention constitutes an omission of elements or parts and its corresponding loss in function.
- (2) All three Offices recognize inventive step when the omission produces an unexpected effect/result. The EPO, however, has commented on its assessment of the effect of omission that "No inventive step is seen if the omission is to reduce the price of product with consequent loss of quality. On the other hand, if the omission results surprisingly in an equal or even better quality, or, successfully goes totally against current technical opinion, then this is taken as a positive indication for there being an inventive step".

g. Change or limitation of use

The practices of the three Offices coincide on the following two points:

- (1) No Office recognizes an inventive step if the invention constitutes a change or limitation of the use of prior art which could have easily been made by a person skilled in the art and which does not produce but a normally expected effect/result.
- (2) All three Offices recognize inventive step when the new feature produces an unexpected effect/result and the choice of the new feature enables the conventional technical expectancy to be surpassed.

The EPO, however, has commented that "In the case of known chemical substances or compositions which are for the first time proposed for use in surgery, therapy or diagnostic methods, a claim limited to that use may be granted provided the use is novel and inventive". The JPO mentions that even if the medicinal use of the claimed medicinal invention differs from the medicinal use of the cited invention, when the relevance of the working mechanism between both has been derived from the publicly known art or common general knowledge at the time of filing, the inventive step of the medicinal invention of the present patent application is usually denied, unless otherwise there is another ground for inferring

inventive step such as advantageous effect or the like.

(Examination Guidelines Part VII. Chapter 3. "Medicinal Inventions" Section 2.3.1.1(1))

h. Selection invention

All three Offices follow the same practice in recognizing inventive step to an invention consisted of particular subordinate ideas contained in prior art if it shows a significant and unexpected result.

i. Others

As a basic rule in the EPO, if, having regard to the state of the art, it would already have been obvious for a skilled person to arrive at something falling within the terms of a claim, for example due to a lack of alternatives thereby creating a "one-way street" situation, the unexpected effect is merely a bonus effect which does not confer inventiveness on the claimed subject-matter.

4. Indication of problem to be solved

The EPO states that "If the problem (to be solved by the invention) itself is judged to be novel and to involve an inventive step, the solution to the problem as expressed in the claims is then deemed to involve an inventive step".

The USPTO stated that in determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. See 35 U.S.C. 103(a).

In the JPO, a close similarity of a problem to be solved can be a strong ground for the reasoning that a person skilled in the art would be led to a claimed invention by applying or combining cited inventions. When a cited invention does not intend a similar problem to be solved to that of a claimed invention, further examination based on the state of the art should be conducted whether a problem to be solved is obvious or whether it would have been easily conceived.

(Examination Guidelines Part II. Chapter 2. Section 2.5(2) )

## 5. Indication of advantage of claimed invention

The USPTO has commented that the USPTO does not require "advantage," in addition to nonobviousness. A claim that contains language setting forth an advantage of the claimed invention over the prior art does not afford the effect of a distinguishing limitation without further structure in the claim and therefore would not constitute an inventive step.

In the EPO's view an advantageous effect is not mandatory and in any case it may be notified later on to the Examiner during the examination procedure.

In the JPO, if an advantageous effect compared to cited inventions can clearly be identified from descriptions in the specification and the drawings, it should be taken into consideration as a fact to support to affirmatively infer its inventive step.

(Examination Guidelines Part II. Chapter 2. Section 2.5(3))

## 6. Comparative test

The result of the comparative test between the claimed invention and the prior art may be used as one of the criteria in determining an inventive step by all three Offices.

The EPO, however, has pointed out that "The comparative tests should only be called for when absolutely necessary".

The USPTO also has commented that "The comparative tests are usually submitted as rebuttal evidence showing unexpected result once the USPTO has established a case of *prima facie* obviousness in view of the prior art. The comparative test data must be between the claimed invention and the closest prior art which is commensurate in scope with the claims."

The JPO has mentioned that where advantageous effects compared to cited inventions are described in a specification, or where advantageous effects are not explicitly described but can be inferred from the statements in the specification or the drawings by a person skilled in the art, the effects asserted in a written argument or verified in experimental results should be considered. However, the effects asserted which are not described in the specification and that a person skilled in the art couldn't deduce from the description of the specification or the drawings should not be taken into consideration. (Examination Guidelines Part II. Chapter 2. Section 2.5(3) )

## 7. Unexpected result

- a. Cases where an unexpected result is an essential criterion for unobviousness (selection inventions and inventions comprising the combination of known elements)

All three Offices follow the same practice in recognizing inventive step in the claimed invention, if it produces an unexpected result.

- b. Cases where it is merely one of a number of relevant secondary criteria

Both the EPO and the USPTO consider "unexpected results" as just one factor that has to be taken into secondary consideration when determining inventive step, whereas the JPO's report states that if an advantageous effect compared to cited inventions can clearly be identified from descriptions in the specification and the drawings, it should be taken into consideration as a fact to support to affirmatively infer its inventive step. (Examination Guidelines Part II. Chapter 2. Section 2.5(3))

- c. Does an unexpected effect (result) have to be advantageous to constitute an inventive step?

Under the three Offices' practice, an unexpected result is not required to be advantageous.

## 8. Others

Each Office made no other comments.

## F. Resolving the level of ordinary skill

1. A person skilled in the art, an average expert

- a. Amount of knowledge and skill expected

Basically, there is no difference of opinion among the three Offices regarding the amount of knowledge and skill expected of the person skilled in the art, or an average expert.

In other words, all Offices consider that the knowledge and skill expected of a person skilled

in the technical field or an average expert means, in general, ordinary knowledge and skill, at the time of filing the application (the JPO and the EPO) or at the time the invention was made (the USPTO), in the technical field to which the invention pertains, in a broader relevant technical field or in the closely related technical fields.

The EPO states in addition that the "person skilled in the art" should be presumed to be an ordinary practitioner in a field of technology aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability.

The JPO states that a person skilled in the art is able to comprehend all technical matters in the state of the art in the field to which a claimed invention pertains at the time of filing as his/her own knowledge. In addition, a person skilled in the art is supposed to be able to comprehend all technical matters in the field of technology relevant to a problem to be solved by an invention as his/her own knowledge. (Examination Guidelines Part II. Chapter 2. Section 2.2(2))

The USPTO's report identified factors that may be considered in determining the level of ordinary skill in the art. The factors are:

- (1) "type of problems encountered in the art;"
- (2) "prior art solutions to those problems;"
- (3) "rapidity with which innovations are made;"
- (4) "sophistication of the technology; and"
- (5) "educational level of active workers in the field."

In a given case, every factor may not be present, and one or more factors may predominate." *In re GPAC*, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995).

The USPTO also noted that in addition to the above factors, examiners may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Court has stated that examiners and administrative patent judges on the Board are

"persons of scientific competence in the fields in which they work" and that their findings are "informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art." In re Berg, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

b. Ordinary practitioner/average expert

There is no essential difference among the three Offices with respect to the definition of ordinary practitioner/average expert.

In fact, an ordinary practitioner/average expert is considered to be a person aware of the common technical knowledge in the relevant art, with ordinary ability to solve the problem by applying such technical knowledge, but not endowed with special creativity or inventive flair.

c. A team of persons skilled in the art

The EPO's and the JPO's reports state that there may be instances where it is more appropriate to think in teams of a group of persons, e.g. a research or production team, rather than a single person.

On the other hand, the USPTO have no provision for "a team of persons skilled in the art".

2. Long-felt but unsolved needs

The EPO and the USPTO take it as one of positive factors in judging the inventive step, if the applicant can show that the invention would satisfy a long-felt but unsolved need.

The JPO mentions that whether or not a claimed invention involves an inventive step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing. (Examination Guidelines Part II. Chapter 2. Section 2.4(1))

3. Prior art teaching away from the claim (technical prejudice)

All three Offices take prior art teaching away from the claim (technical prejudice) into account as a positive factor in judging the inventive step.

The JPO's report states that regardless of the description in a cited reference such as the difference of the problem to be solved, which prima facie precludes the reasoning, the eligibility for a cited invention shall be maintained, if the reasoning could be possible in terms of other aspects such as a close relation of technical fields or close similarity of function, work or operation, etc. (Examination Guidelines Part II. Chapter 2. Section 2.8)

The EPO and the USPTO state in their reports that there is, as a general rule, inventive step when prior art leads a person skilled in the art away from the claim. The USPTO also noted that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness, however, the nature of the teaching is highly relevant and must be weighed in substance.

#### 4. Showing the failure of others

The EPO and the USPTO consider the failure of others as a positive factor in judging inventive step.

As to the JPO practice, see F.2. above.

#### 5. Showing that the invention lies in a very active or crowded art

The EPO takes into consideration the fact that an invention lies in a very active or crowded art while examining the present state (peculiarity) of the technical field in question. This fact is judged together with other tests when assessing inventive step.

The EPO's report, in addition, states that the fact that an invention lies in a very active or crowded art may lead to cases where even a smaller step might be considered sufficient to constitute inventive step, if the state of the art is such as to leave limited room for further advances.

On the contrary, the USPTO's report states that the fact an invention lies in a very active or a crowded art does not mean that smaller steps forward would therefore constitute an inventive step. The criteria for determining obviousness is based upon the factual inquiries set forth by the Supreme Court in *Graham v. John Deere*. The key to supporting any rejection under 35 U.S.C. 103 is

the clear articulation of the reason(s) why the claimed invention would have been obvious to one of ordinary skill in the art.

6. Development of brand-new technical field

The EPO takes the fact of developing a brand-new technical field into consideration when assessing inventive step. Where the technology involved concerns a brand-new field, inventive step may be more likely to be present if:

o there is no relevant prior art, or

o if the closest prior art is fairly distant from the invention at hand.

The JPO and the USPTO state that there is no special consideration or different standards of obviousness given in evaluating the inventive step for an invention directed to brand-new technical field. The USPTO also states that the examiner evaluates the totality of the claim and makes a determination based on the factual inquiries set forth in the *Graham v. John Deere* decision.

7. Commercial success

All three Offices do not consider the commercial success alone as indicative of inventive step, but take it into account in judging the inventive step only when the success is derived from the technical features of the claimed invention.

8. Complexity of the technology

The JPO and the EPO do not give a definite role to the complexity of the technology in judging the inventive step, but consider it in the current situation (peculiarity) of the technical field in question, and make judgment in combination with other tests.

The USPTO's report states that there is no special consideration or different standards of obviousness given in evaluating the inventive step because of the complexity of the technology. The examiner evaluates the totality of the claim and makes a determination based on the factual inquiries set forth in the *Graham v. John Deere* decision.

## II. Special consideration applicable to chemical practice

### A. Criteria used to determine the inventive step based upon

#### 1. a. Unexpected or superior properties of a chemical

There is no difference in practice among the three Offices with respect to recognizing inventive step when a substance having a similar chemical structure to a known chemical possesses an unexpected property, i.e. a new property, or a superior effect with regard to the same property. The reasoning of each Office is as follows:

JPO: In the above case, an invention involves an inventive step, when it generates an advantageous effect which is qualitatively different or qualitatively the same but quantitatively prominent in comparison with that of an invention with a generic concept in a cited invention, neither of which is foreseen by a person skilled in the art from the state of the art nor disclosed in a cited reference. (Examination Guidelines Part II. Chapter 2. Section 2.5(3) )

EPO: The level of predictability is much lower for chemicals than it is for inventive features in other fields.

USPTO: A chemical composition and its properties are inseparable. Furthermore, evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to support a determination that the claimed invention would not have been obvious.

#### b. Determination of inventive step between chemical substances of similar structure

Is a newly discovered property of the novel chemical compound having similar structure to a known chemical compound, which property is inherent to the known chemical compound, but not disclosed in the prior art, favorably taken into account when determining inventive step of the novel chemical compounds?

Under the USPTO practice, the mere discovery of a property lacks inventive step, where the property is inherent in a structurally similar chemical compound known in the art, even though the property is not disclosed in the known prior art compound.

Under the EPO practice, if the compounds of the prior art were described as having a different effect, unrelated to the one exhibited by the new compounds, or no effect at all, inventive step of said effect will be acknowledged by the examiner provided he is satisfied that the effect of the new compounds is unexpected in view of what the prior art teaches.

## 2. Evidence required to evaluate therapeutic properties

In the JPO, as for working examples supporting the medicinal use, a description of the result of the pharmacological test is usually required. Since the result of the pharmacological test is to confirm the pharmacological effect of the claimed medicinal invention, all of the followings should be made sufficiently clear, in principle; (i) which compound is, (ii) applied to what sort of the pharmacological test system, (iii) what sort of result is obtained, and (iv) what sort of relationship the pharmacological test system has with the medicinal use of the claimed medicinal invention.

The EPO considers tests conducted on animals or in vitro to be sufficient except in cases where, owing to the content of the invention, only clinical (human) tests could prove the invention's therapeutic properties.

The USPTO mentions that evidence submitted to support patentability is relevant provided there is a reasonable correlation between the claimed invention and such evidence. See MPEP 2107.02. Further, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for the USPTO personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See MPEP 2107.03. The USPTO have made mention of accepting animal experiments or in vitro tests in place of clinical tests depending on the contents of the invention, it seems that after all the three Offices apply the same principles in their practice.

The JPO mentions that in the claimed medicinal invention defined by a combination of two or more medicinal components, when the combination of the components is novel and a remarkable effect is performed by the combination of two or more compounds or groups of compounds, the claimed medicinal invention can involve an inventive step.

## 3. Intermediates

In the USPTO the term "intermediate" as used here means intermediate or starting products which are, according to the patent application, described for their ability to be used to produce final

products through a reaction in which the intermediate loses its identity.

In the EPO, the expression "intermediate products" means compounds which do not necessarily have any useful direct application but which serve as starting or intermediate substances for producing other subsequent chemical substances (end products) by chemical reaction in an inventive process. In addition, the EPO distinguishes between two categories of possibly patentable intermediates (a) intermediates for a known end-product as a step in an inventive process and (b) intermediates for an inventive end-product through an obvious process. Requirements for inventive step are set accordingly in each of the two cases.

The JPO mentions that there are no criteria used to determine the inventive step based upon intermediates..

The USPTO evaluates the obviousness of chemical intermediates in the same manner as other chemical compounds. Thus the patentability of a chemical intermediate may be established by unexpected properties of an end product when the claimed intermediate contributes to such an unexpectedly superior activity or property. If applicant claims an unstable and transitory chemical intermediate, the enablement requirement does not require that the applicant teach how to make the product in stable, permanent, or isolatable form, however the chemical intermediate must have a specifically identified substantial utility.

#### 4. Inventive step of invention defined by parameters (e.g. numerical formula)

With respect to the application of parameters, the EPO allows their use only when the invention cannot be adequately defined with other methods.

The USPTO permits applicants to claim an invention defined by parameters even when invention can be adequately defined by other methods.

In judging inventive step, each Office requires consideration not only of the parameters but also of other matters described in the claim.

The JPO mentions that where a claim includes statements defining a product by its function or characteristic, etc. and it falls under either the following or , there may be cases where it is difficult to compare the claimed invention with a cited invention. In the above circumstances, if the examiner has a reason to suspect that the claimed product would

be prima facie similar to the product of the cited invention and that the claimed invention would prima facie involve no inventive step without making a strict comparison of the claimed product with the product of the cited invention, the examiner may send the notice of reasons for refusal under Article 29(2).

Then an applicant may argue or clarify by putting forth a written argument or a certificate of experimental results, etc. against the notice of reasons for refusal.

The reason for refusal is to be dissolved if the applicant's argument succeeds in changing the examiner's evaluation at least to the extent that it is unclear that the claimed product is prima facie similar to the product of the cited invention and that the claimed invention would prima facie involve no inventive step.

Where the applicant's argument, which is, for example, abstract or general, does not change the examiner's evaluation to that extent, the examiner may make a decision of refusal under Article 29(2).

A case where the function or characteristic, etc. is neither standard, commonly used by a person skilled in the art in the relevant technical field nor comprehensible of its relation to a commonly used function or characteristic, etc. to a person skilled in the art if the function or characteristic is not commonly used; or

A case where plural of functions or characteristics, etc. each of which is either standard, commonly used by a person skilled in the art in the relevant technical field or comprehensible of its relation to a commonly used function or characteristic, etc. to a person skilled in the art if the function or characteristic is not commonly used, are combined in a claim so that the claim statements as a whole fall under .

(Examination Guidelines Part II. Chapter 2. Section 2.6(1))

## 5. Other criteria

### a. Characteristic of manufacturing method of a chemical substance and an inventive step as an invention of chemical substance

In the EPO practice, as to a chemical substance defined by its process of manufacture, the EPO recognizes inventive step by the process of manufacture alone. In the USPTO it is the patentability of the product, not recited process steps, that must be evaluated in product-by-process type claims.

The JPO mentions that, if a claim is one with statements defining a product by its manufacturing

process, there may be cases where it is difficult to determine what the product per se structurally is. In such circumstances, if the examiner has a reason to suspect that the claimed product would be prima facie identical with the product of the cited invention and that the claimed invention would prima facie involve no inventive step without making a strict comparison of the claimed product with the product of the cited invention, the examiner may send the notice of reasons for refusal under Article 29(2).

(Examination Guidelines Part II. Chapter 2. Section 2.7(1))

## B. Criteria to evaluate compositions or structures

### 1. Chemical product patentable per se

The EPO states that a chemical product may be considered as having inventive step simply based on structural non-obviousness if it is structurally very different from any known compounds and there is no similar known compounds.

The JPO mentions that whether or not a claimed invention involves an inventive step is determined whether the reasoning that a person skilled in the art could have easily arrived at the claimed invention based on cited inventions can be made by constantly considering what a person skilled in the art would do after precisely comprehending the state of the art in the field to which the present invention pertains at the time of the filing.

(Examination Guidelines Part II. Chapter 2. Section 2.4(1))

In the USPTO, chemical products are patentable, per se, as compositions of matter, if they satisfy the utility, novelty, nonobviousness, written description, and enablement requirements of the patent statute.

However, there is no substantial difference among three Offices as to a chemical product patentable per se, because there is a tendency in the EPO also to refuse patentability of a product which exhibits no usefulness, on the ground that there would be lack of industrial application.

### 2. Structural obviousness in chemical cases

The EPO and the USPTO share common practice in determining the inventive step of a chemical product, with emphasis on

o chemical structure, and

o properties (qualitative and/or quantitative). The question in determining inventive step of a chemical product from the viewpoint of its chemical structure, is whether the relation between the chemical structure and its properties is predictable (expected) or not. In short, if one property is unexpected, the chemical product will be considered as being inventive even if its chemical structure is similar to that of a known chemical product.

As to the JPO practice, reasoning whether or not a claimed invention involves an inventive step is attempted by confirming and taking into consideration an advantageous effect, if any, of a claimed invention compared to cited inventions. In the case of an invention in a technical field in which an effect of a product is difficult to predict from its structure, the advantageous effect compared to the cited invention is an important fact to positively infer its inventive step.

(Examination Guidelines Part II. Chapter 2. Section 2.5(3) )

### 3. Purer form of known product

The EPO and the USPTO share the view that inventive step cannot be recognized for purer form unless it possesses some unexpected property from corresponding known product (simple improvement in purity is not sufficient).

As to the JPO practice, see II.B.1 above.

### 4. Novel physical forms; e.g. new crystalline structure

There is no difference in practice between the EPO and the USPTO, as both Offices treat products with novel physical forms as not having inventive step unless they show unexpected properties which were not known for the previously disclosed other physical forms.

As to the JPO practice, see II.B.1 above.

### 5. Products of nature

All three Offices follow the same practice of not granting a patent to products of nature.

However, all three Offices state that they may recognize inventive step on chemical substances isolated from nature if they show unexpected properties.

6. Effects of components of a mixture

There is no fundamental difference among the three Offices with respect to the judgment criterion for inventive step of mixtures.

In short, all Offices do not recognize inventive step for a mixture that exhibits only an effect in the extent expected from the effects of each component (the arithmetic sum of effects).

7. Various chemical forms of a compound; e.g. isomers

All three Offices basically share the same view as to the inventive step for isomers.

In brief, the judgment depends upon whether or not the isomer in question possesses an unexpected property compared to corresponding chemical compounds, and corresponding isomers.

The USPTO's report further explains that isomers that have the same empirical formula but different structures are not necessarily considered equivalent by chemists skilled in the art and therefore are not necessarily suggestive of each other.

C. Criteria for chemical processes; e.g. process producing known chemical product, old process using new starting materials, etc.

The practice applied by the EPO is that a process claim based on a known reaction is considered as being inventive when,

- (1) the product obtained therefrom satisfies the requirements of patentability (novelty and inventive step), or
- (2) the process itself, due to the specific means or conditions applied, produces an unexpected result.

The USPTO practice is limited to the situation described in (2), above. That is, the process itself must be patentable and may not merely rely upon the recitation of a patentable product for patentability.

The JPO practice is that where an invention of a product per se involves an inventive step, inventions of a process of producing the product or of a use of the product involves an inventive step in principle. (Examination Guidelines Part II. Chapter 2. Section 2.8(5))

D. Other considerations to determine the inventive step in chemical practice

1. Secondary tests (subtests) of non-obviousness

All three Offices do not employ any secondary tests or subtests different from those applied in other technical fields in judging inventive step in the chemical field.

2. Extent to which comparative tests are required

All three Offices include comparative tests as a measure in judgment inventive step.

(1) Requirement of comparative test

In the EPO, comparative tests may be filed in support of a patent application when the difference in effect between the invention and the known art must be clarified and no other evidence is available to support the existence of inventive step.

While the USPTO's report explains that it does not require applicants to submit comparative tests, it mentions that comparative tests, usually submitted as rebuttal evidence, are considered when making a final determination of obviousness or nonobviousness.

The JPO states that where advantageous effects compared to cited inventions are described in a specification, or where advantageous effects are not explicitly described but can be inferred from the statements in the specification or the drawings by a person skilled in the art, the effects asserted or verified (e.g., experimental results) in a written argument, etc. should be considered. However, the effects asserted in the written argument, which are not described in the specification and that a person skilled in the art couldn't deduce from the description of the specification or the drawings, should not be taken into consideration.

(Examination Guidelines Part II. Chapter 2. Section 2.5(3) )

(2) Arts to be compared

The reports of the EPO and the USPTO state that the claimed invention should be compared against the closest prior art.

3. Others

Each Office made no other comments.

**Appendix I-1.**

**Article 29 of Japanese Patent Act (Conditions for Patentability)**

- (1) An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following:
- (i) inventions that were publicly known in Japan or a foreign country, prior to the filing of the patent application;
  - (ii) inventions that were publicly worked in Japan or a foreign country, prior to the filing of the patent application; or
  - (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the patent application.
- (2) Where, prior to the filing of the patent application, a person ordinarily skilled in the art of the invention would have been able to easily make the invention based on an invention prescribed in any of the items of the preceding paragraph, a patent shall not be granted for such an invention notwithstanding the preceding paragraph.

**Appendix I-2.**

Art 56 of the European Patent Convention (EPC)- Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.

### **Appendix I-3.**

#### **35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

#### **37 CFR 1.104 Nature of examination.**

(a) *Examiner's action.*

(1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

(2) The applicant, or in the case of a reexamination proceeding, both the patent owner and the requester, will be notified of the examiner's action. The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant, or in the case of a reexamination proceeding the patent owner, to judge the propriety of continuing the prosecution.

(3)An international-type search will be made in all national applications filed on and after June 1, 1978.

(4)Any national application may also have an international-type search report prepared thereon at the time of the national examination on the merits, upon specific written request therefor and payment of the international-type search report fee set forth in § 1.21(e). The Patent and Trademark Office does not require that a formal report of an international-type search be prepared in order to obtain a search fee refund in a later filed international application.

(b)*Completeness of examiner's action.* The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

(c)*Rejection of claims.*

(1)If the invention is not considered patentable, or not considered patentable as claimed, the claims, or those considered unpatentable will be rejected.

(2)In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

(3)In rejecting claims the examiner may rely upon admissions by the applicant, or the patent owner in a reexamination proceeding, as to any matter affecting patentability and, insofar as rejections in applications are concerned, may also rely upon facts within his or her knowledge pursuant to paragraph (d)(2) of this section.

(4)Subject matter which is developed by another person which qualifies as prior art only under 35 U.S.C. 102(e), (f) or (g) may be used as prior art under 35 U.S.C. 103 against a claimed invention unless the entire

rights to the subject matter and the claimed invention were commonly owned by the same person or subject to an obligation of assignment to the same person at the time the claimed invention was made.

(i) Subject matter developed by another person and a claimed invention shall be deemed to have been commonly owned by the same person or subject to an obligation of assignment to the same person in any application and in any patent granted on or after December 10, 2004, if:

(A) The claimed invention and the subject matter was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) The claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) The application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(ii) For purposes of paragraph (c)(4)(i) of this section, the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

(iii) To overcome a rejection under 35 U.S.C. 103(a) based upon subject matter which qualifies as prior art under only one or more of 35 U.S.C. 102(e), (f) or (g) via 35 U.S.C. 103(c)(2), the applicant must provide a statement to the effect that the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement, within the meaning of 35 U.S.C. 103(c)(3) and paragraph (c)(4)(ii) of this section, that was in effect on or before the date the claimed invention was made, and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement.

(5) The claims in any original application naming an inventor will be rejected as being precluded by a waiver in a published statutory invention registration naming that inventor if the same subject matter is claimed in the application and the statutory invention registration. The claims in any reissue application naming an inventor will be rejected as being precluded by a waiver in a published statutory invention registration naming that inventor if the reissue application seeks to claim subject matter:

(i) Which was not covered by claims issued in the patent prior to the date of publication of the statutory invention registration; and

(ii) Which was the same subject matter waived in the statutory invention registration.

(d) *Citation of references.*

(1) If domestic patents are cited by the examiner, their numbers and dates, and the names of the patentees will be stated. If domestic patent application publications are cited by the examiner, their publication number, publication date, and the names of the applicants will be stated. If foreign published applications or patents are cited, their nationality or country, numbers and dates, and the names of the patentees will be stated, and such other data will be furnished as may be necessary to enable the applicant, or in the case of a reexamination proceeding, the patent owner, to identify the published applications or patents cited. In citing foreign published applications or patents, in case only a part of the document is involved, the particular pages and sheets containing the parts relied upon will be identified. If printed publications are cited, the author (if any), title, date, pages or plates, and place of publication, or place where a copy can be found, will be given.

(2) When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.

(e) *Reasons for allowance.* If the examiner believes that the record of the prosecution as a whole does not make clear his or her reasons for allowing a claim or claims, the examiner may set forth such reasoning. The reasons shall be incorporated into an Office action rejecting other claims of the application or patent under reexamination or be the subject of a separate communication to the applicant or patent owner. The applicant or patent owner may file a statement commenting on the reasons for allowance within such time as may be specified by the examiner. Failure by the examiner to respond to any statement commenting on reasons for allowance does not give rise to any implication.

## Appendix II-1

For the [Examination Guidelines for Patent and Utility Model in Japan](#),  
go to [http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki\\_e/t\\_tokkyo\\_e/1312-002\\_e.htm](http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm)

**Appendix II-2.**

Current version of the Guidelines for examination in the European Patent Office:

<http://www.epo.org/patents/law/legal-texts/guidelines.html>

**Appendix II-3**

For the current version of the MPEP, go to <http://www.uspto.gov/web/offices/pac/mpep/index.htm>.