

COMPARATIVE STUDY REPORT

ON

Novelty

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A. Judicial, legislative or administrative criteria or guidelines for determining novelty

- o All the provisions cited below refer to the version of the European Patent Convention (EPC) which entered into force on December 13, 2007. Depending on the effective date of filing or the date of the decision to grant, a number of Articles and Rules of the previous version may still apply. For details, see the transitional measures as published in the EPO Official Journal (available on the EPO Internet Site <http://www.epo.org>).
- o The Implementing Rules as well as the Guidelines are subject to amendments, depending on changes in policy and/or practice (a new cycle of revision is running). It is therefore recommended to rely solely on the latest version of these provisions, transitional measures and Guidelines as published on the EPO Internet Site, where further publications of interest, such as the whole case law relating to European patents or the Case Law Reports, are also available.

1. Legislation (law and regulations)

- o Article 29 (1) of the Patent Act
- o Article 29 (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

- EUROPEAN PATENT CONVENTION** (as entered into force on December 13, 2007)
- Articles directly related to the requirement of novelty:
- o Art. 52(1) EPC: Novelty as a fundamental requirement for patentability
 - o Art. 54 EPC: Relevant definitions and conditions of application: novelty and state of the art, including conflicting applications, exceptions relating to medical uses of known substances and compositions

- o 35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent
A person shall be entitled to a patent unless -
 - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, or
 - (b) the invention was patented or described in a printed publication in this or a foreign

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(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.

- o Art. 55 EPC: Non-prejudicial disclosures
- o Art. 97(2) EPC: Lack of novelty a ground for refusing grant
- o Art. 100(a) EPC: Lack of novelty a ground for opposition to a granted patent
- o Art. 124 EPC: Information on prior art in other national/regional proceedings relating to the same invention

Other articles of relevance:

- o Art. 53(c) EPC: Claims directed to medical uses of known products or compositions in therapeutic methods which are otherwise excluded from patentability
- o Art. 80 EPC: Date of filing (as to the determination of the relevant date for the assessment of availability to the public)
- o Art. 83 and 84 EPC: Respectively, disclosure in the application of the invention and definition in the claims of the matter for which protection is sought, to the extent they are relevant for claim interpretation
- o Art. 87 to 89 EPC: Priority rights (as to the critical date for the assessment of novelty)
- o Art. 138(1) (a) EPC: Lack of novelty a ground for revocation of a patent in national proceedings

Implementing Rules (subject to amendments, see latest version on the EPO Internet Site)

- o Rule 40 and Rule 52 EPC: Date of filing or date of earliest priority (for establishing the critical date for assessment of novelty)
- o Rule 42 and Rule 43 EPC: Content

country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, or

- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or
- (f) he did not himself invent the subject matter sought to be patented; or

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of the description, form and content of the claims, to the extent they are relevant for claim interpretation

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

2. Guidelines

o Examination Guidelines Part II. Chapter 2 "Novelty and Inventive step" Section 1. "Novelty"

The sections listed below are those of the "**Guidelines for Examination in the European Patent Office - Status April 2009**" (hereafter, "GL").

Please note that the Guidelines have entered a new cycle of revision steps, which may ultimately affect the overall organisation of the contents. Therefore, references to the current guidelines within the sections of the comparative table have been avoided. It is recommended to rely solely on the latest version of the Guidelines as published on the EPO Internet Site.

o GL-C-III: Claims (in particular

o MPEP 706.02 to 706.02(i) and 2131 to 2138.06.
o For rejections based on 35 U.S.C. 102(a), see MPEP 706.02(a) and (c) and 2132.
o For rejections based on 35 U.S.C. 102(b), see MPEP 706.02(a) and (c) and 2133.
o For rejections based on 35 U.S.C. 102(c), see MPEP 706.02(d) and 2134.
o For rejections based on 35 U.S.C. 102(d), see MPEP 706.02(e) and 2135 to 2135.01.
o For rejections based on 35 U.S.C. 102(e), see MPEP 706.02(f) to (f) (2) and 2136 to 2136.04.
o For rejections based on 35 U.S.C. 102(f), see MPEP 706.02(g) and

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		for all aspects of claim presentation, wording or interpretation)	2137.
		o GL C-IV, 6: State of the art	o For rejections based on 35 U.S.C. 102(g), see MPEP 706.02(h) and 2138 to 2138.06.
		o GL C-IV, 9: Novelty in examination	
		o GL D-V, 3: Novelty objections likely to arise in post-grant proceedings, and in particular objections based on non-written prejudicial disclosures such as prior use, oral descriptions, etc ...)	
<hr/>			
3. <u>Background and purpose of the provision relating to novelty</u>	o The purpose of the Patent System is to grant an exclusive right that is a reward for the disclosure of an invention, so that an invention which deserves a patent should be novel. The provision of Patent Act Article 29(1)(i) to (iii) categorizes inventions lacking novelty, in order to define the scope of such inventions.	o Art. 52(1) EPC makes novelty one of the fundamental requirements for patentability. The 20-year monopoly granted to an applicant in the form of a European patent is basically considered as a fair compensation (or a "reward") for making the technical information relating to a new invention available to the public. Thus, the purpose of the requirement of novelty is to bar the grant of a patent for subject-matter already known in the state of the art.	o Under U.S. patent law, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." (35 U.S.C. 101) A patent shall be granted if all conditions for patentability are satisfied (e.g., 35 U.S.C. 101, 102, 103 and 112). In exchange for the rights grant by a patent (35 U.S.C. 154(a)), the claimed invention must satisfy the conditions for patentability, one of the conditions for patentability being that the claimed invention must be novel. For a rejection based on 35 U.S.C. 102, lack of novelty, the reference must teach every aspect of the claimed invention either explicitly or impliedly.
		o Art. 54(1) EPC states that "an invention shall be considered to be new if it does NOT form part of the state of the art" (highlight added). In other words, it is for the Examiner (or for the parties involved in post-grant proceedings) to put forward convincing evidence of lack of novelty, and not for the applicant to prove that his invention is novel.	
		o The requirement of novelty under the EPC is a requirement of absolute novelty . It is assessed against "everything made available to the public" (Art.	

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54(2) EPC) by any means, anywhere in the world, provided the date of availability to the public can be clearly established.

- o In the EPO, assessment of novelty occurs in both pre-grant and post grant proceedings. In order to avoid unnecessary repetition of the expressions "Examining Division" or "Opposition Division", the generic expression "Examiner" has been used instead. This, however, does not affect the general principle that decisions on patentability rest with the Examining Divisions or Opposition Divisions acting as collegiate bodies.

B. Determining the scope of the claimed invention

1. Basic principles of interpretation of claims

- o The finding of a claimed invention should be made on the basis of the statements of the claim. Matters (terms) stated in the claim defining the claimed invention should be construed in the light of the description in the specification (excluding the claim(s)) (hereinafter referred to as "description", the drawings and the common general knowledge as of the filing.
(Examination Guidelines Part II. Chapter 2. Section 1.5.1)

- Before assessment of novelty starts, the Examiner will first check:
- o whether the factual situation has changed, e.g., whether claims have been amended or withdrawn
 - o whether unsearched subject matter that does not combine with the originally claimed invention (or original single general inventive concept) under Rule 137(4) EPC is still present in or has been introduced into the claims
 - o whether the requirement of unity under Art. 82 EPC is met (or still met)
 - o whether the requirements of clarity under Art. 83 EPC and support of the claims in the description under Art. 84 EPC are met (or still met).

- o During patent examination, the claims must be "given their broadest reasonable interpretation consistent with the specification." See Phillips v. AWH Corp., 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc). This is because applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 162 USPQ 541, 550-51 (CCPA 1969).
- o See also MPEP 2111.

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a. Wording of the claims

- o When the claim statements are clear, the finding 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.
(Examination Guidelines Part II. Chapter 2. Section 1.5.1(1))

- o Claims must clearly define the subject-matter of the invention, that is to say, indicate all the essential features thereof (see T 32/82, OJ 8/1984, 354).
- o They must be comprehensible from a technical point of view, e.g., they must be drafted in terms of the "technical features of the invention". Any technical feature which is consistently described to be essential to the invention must be incorporated in the claims.
- o Technical features may be expressed as structural or functional features. Non-technical features, to the extent that they do not interact with the technical subject matter of the claim for solving a technical problem, will be ignored in assessing novelty.
- o The wording of a claim must allow the person skilled in the art to understand what falls within the scope of the claim and what does not. Words will be given the meaning and scope which they normally have in the relevant field, unless otherwise and explicitly specified.
- o It is admitted that **claims are normally generalisations that encompass more than the embodiments described therein**. It is the invention as claimed, and not merely as described in the form of one or several embodiments, that is being examined for novelty.

The first step of assessment of novelty is to establish the true meaning and scope of the claims.

This, however, implies establishing

- o During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of a claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. In re Zletz, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Plain meaning refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art. See Phillips v. AWH Corp., 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) (en banc). Applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 53 USPQ2d 1065, 1069 (Fed. Cir. 1999).
- o "Although understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." Superguide Corp. v. DirectTV Enterprise, Inc., 69

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- first:
- o the claim category (Rule 43(2) EPC), regardless to the way the characterising technical features are defined. Claims may be directed to either entities (products, compositions, apparatuses, devices, etc ...) or activities (processes or uses). If the category of a claim is ambiguous, e.g., it is unclear whether it is directed to an entity or an activity, the applicant will be invited to clarify the matter by rewording the claim.
 - o the type of claim, regardless to the way a claim is actually drafted. A correct identification of the type of a claim is important for a number of practical reasons. Assessment of novelty is made on independent claims only, subject to some exceptions on a case-by-case basis. Novelty of a process claim for a process resulting inevitably in the product as described in the product claim referred to, with all the features defined therein, need not be established separately if the product is novel.
 - o Concealed independent claims: A claim referring to another claim may be a concealed independent claim, in which case it will require separate assessment of novelty.
 - o "US-type claims" (e.g., sets of claims with many independent claims of overlapping scope) will in most of the cases lead to an objection of lack of clarity under Art. 84 EPC together with Rule 43(2) EPC. It is therefore

USPQ2d 1865, 1868 (Fed. Cir. 2004).
o See MPEP 2111.01.

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highly recommended to avoid this type of claims in an European patent application.

The second step is assessment of clarity.

- o Clarity of the claims is of the utmost importance in view of their function in defining the matter for which protection is sought. The requirement of clarity applies to individual claims and to the claims as a whole.
- o Independent claims must contain all the technical features that are essential to the performance of the invention, e.g., to the solution of the problem to which the invention relates.
- o **The meaning of the terms of a claim must be clear** for the person skilled in the art **from the wording of the claim alone**, and the applicant may be invited to amend the claims accordingly.

A number of items call specific comments, and in particular:

- o Special meanings of words: The applicant may "act as its own lexicographer". However, if the special meaning of a word is given in the description only, the applicant will be required to amend the claims accordingly.
- o Terms introducing ambiguity in a claim: They will have to be clarified, unless they have a well-recognised meaning in the relevant technical field. In particular, relative terms, approximate terms, unusual technical terms, optional features, trademarks, etc ... will be considered as

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inappropriate for a clear definition of the subject matter for which protection is sought.

- o Parameters: Characterisation of a product or process by its parameters should be avoided, unless the invention cannot be defined in another way, and provided these parameters can be clearly and reliably determined either by indication in the description or by objective procedures which are usual in the art. Obscure, unusual or insufficiently defined parameters will lead to an objection of lack of clarity under Art. 84 EPC.

b. Consideration of the description and drawings

- o Even though the claim statements are clear, however, when terms or language used in the claim (matters defining the claimed invention) are defined or explained in the description or the drawings, the definition or explanation should be considered when the terms or language are construed. A mere illustrating of more specific concepts of the claims, which is described in the description or the drawings, does not correspond to the definition or the explanation mentioned above.
- o When statements in a claim are unclear or difficult to understand, but can be clarified by considering terms or language in the light of the description, the drawings and the common general knowledge as of the filing, the terms of language should be considered to construe the statements in the claim. (Examination Guidelines Part II. Chapter 2. Section 1.5.1(2))

- o Since the extent of the protection conferred by a European patent or application is determined by the claims, interpreted with the help of the description and the drawings, the claims must be fully supported by the description and drawings. This means that there must be a basis in the description for the subject-matter of every claim and that the scope of the claims must not be broader than is justified by the extent of the description and drawings on the one hand, and the claimed contribution to the art on the other hand (T 409/91, OJ 9/1994, 653).
- o Assessment of the extent of generalisation permissible is a matter for the Examiner to decide on a case by case basis. It will generally include all the variants possibly covered by the claims which have the properties or uses ascribed in the description.
- o Inconsistencies between the

- o The ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Phillips v. AWH Corp., 75 USPQ2d 1321, 1327 (Fed. Cir. 2005) (en banc). It is important to remember that it is improper to import into a claim limitations that are not part of the claim.
- o See MPEP 2111.01.

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- o If a claimed invention is not clear, even by considering the description, the drawings and the common general knowledge as of the filing, the finding of the claimed invention should not be conducted.

(Examination Guidelines Part II.
Chapter 2. Section 1.5.1(3))

- o If there is inconsistency between an invention found in a claim and an invention described in the description or the drawings, the finding and examination of an invention should not be made solely on the basis of the description or the drawings, disregarding the statements of the claim.

- o Even though they are described in the description or the drawings, matters (terms or language), not stated in a claim, should not be treated as they do exist in the claim when the finding of the claimed invention should be made. On the other hand, matters (terms or language) stated in a claim should be always considered and should not be treated as they do not exist in the claim.

(Examination Guidelines Part II.
Chapter 2. Section 1.5.1(4))

claims and the description and drawing(s), or between claims, must be cured by amending the claims and/or description, whichever fits better to the particulars of the case.

2. Inventions claimed in specific forms of definition

a. Products defined by their function, properties, characteristics or mode of operation

- o When a claim includes an expression specifying a product by its function, properties, etc. , such an expression should, in principle, be construed as every product that has such function, properties, etc., except when it should be

Products defined by their function:

- o It is not necessary that every feature be expressed in terms of a structural limitation in a product claim. Functional features may be included, on condition that the skilled person is able to provide some means of

- o A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in

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construed as different meanings according to B.1.b. (see, Note below) For example, "a building-wall material incorporating a layer that insulates heat" should be construed as a building-wall material incorporating "a product" that has "a layer capable of performing a work or function of heat-insulation."

(NOTE) For example, if a claim includes "heat-resistant alloy comprising a composition of..." and the expression "heat-resistant alloy" should be construed as "alloy used for a purpose of requiring heat resistance" as a result of finding the claimed invention by considering the description, drawings and the common general technical knowledge as of the filing, the examiner should follow the guidelines set forth in B.2.b.

(Examination Guidelines Part II.

Chapter 2. Section 1.5.2(1))

o However, if the function, properties, etc. is inherent in the product, such statement does not help to specify the product and it should be construed as the product itself.

(Examination Guidelines Part II.

Chapter 2. Section 1.5.2(1))

o There are also cases where a statement specifying a product by its function, properties, etc. should not be construed as a specific product among all products that have such function, characteristic, etc. by considering the common general technical knowledge as of the filing.

performing this function without exercising inventive skill.

o If, on the other hand, the entire contents of the application is such as to convey the impression that a function is to be carried out in a particular way, and the claim is formulated in such a way as to embrace other means, or all possible means, of performing the function, then objection arises.

o Furthermore, it may not be sufficient if the description merely states in vague terms that other means may be adopted, if it is not reasonably clear to the person skilled in the art what they might be or how they might be used.

o Claims which would attempt to define the invention by a result to be achieved will normally not be allowed, except where the invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims, and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation (T 68/85, OJ 6/1987, 228).

o Subject-matter defined by means of functional features in a claim is to be read in its broadest technically meaningful sense. If, however, the application taken as a whole conveys the impression that a function is to be carried out in a particular way, and the

functional terms. Functional language does not, in and of itself, render a claim improper. In re Swinehart, 169 USPQ 226 (CCPA 1971). A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

o When the claimed product and the prior art product are identical in structure, a prima facie case of anticipation has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). See also Titanium Metals Corp. v. Banner, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.)

o While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure

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- o For example, if a claim includes "a means for fixing the first wooden member to the second plastic member," it is obvious that "a means for fixing" does not represent a fixation means used for metals, such as welding, among all fixation means.
(Examination Guidelines Part II. Chapter 2. Section 1.5.2(1))

claim is formulated in such a way as to embrace other means or all means, of performing the function, an objection of lack of support will arise (Guidelines, C-III, 6.5.).

Products defined by their properties, characteristics or mode of operation:

- o Exceptionally, a product may be defined by its parameters if the invention cannot be adequately defined in any other way, and provided that those parameters can be clearly and reliably determined either by indications in the description or by objective procedures which are usual in the art (see T 94/82, OJ 2/1984, 75).
- o Parameters are characteristic values, which may be values of directly measurable properties (e.g. the melting point of a substance, the flexural strength of a steel, the resistance of an electrical conductor) or may be defined as more or less complicated mathematical combinations of several variables in the form of formulae.
- o When the properties of a material are referred to, the physical values must be expressed in the units recognised in international practice, which is generally in the metric system. Values in the inch/pound system, in general, do not meet the criterion "recognised in international practice".
- o As a more general rule, use should be made of the technical terms, signs and symbols generally accepted in the

rather than function. In re Schreiber, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

- o See MPEP 2114.
- o "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 136 USPQ 458, 459 (CCPA 1963)).
- o See MPEP 2115.
- o Note that under U.S. law, 35 U.S.C. 112, 6th paragraph, applicant is permitted to express a claim limitation in "means-plus-function" language without the recital of structure or material. If applicant invokes 35 U.S.C. 112, 6th paragraph, then that claim limitation will be

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relevant technical field.

- o Claims directed to products defined by their mode of operation in the field of computer-related inventions:

Claims directed to products defined by their mode of operation in the field of computer-related inventions are currently the subject of a referral to the Enlarged Board of Appeal (referenced under G 3/08; further information available on the EPO Internet Home Page).

interpreted by the examiner to cover the corresponding structure or material described in the specification and equivalents thereof. See In re Donaldson, 29 USPQ2d 1845 (Fed. Cir. 1994) and MPEP 2181.

- o If 35 U.S.C. 112, 6th paragraph is invoked by the applicant, the application of the prior art reference to a means-plus-function limitation requires that the prior art element perform the identical function specified in the claim and the prior art structure or material is the same as or equivalent to the structure or material described in specification which has been identified as corresponding to the claimed means-plus-function limitation. See MPEP 2182.

b. Products or processes defined by their use for ... (e.g. "for use as ...", "apparatus for ...", "Method for ...")

- o When a claim includes a statement specifying a product by its use, such as "for use as ..." (i.e. limitation of use), the examiner should determine the meaning of the limitation of use to specify the claimed invention by considering the description, drawings and the common general technical knowledge as of the filing. (Note that when the examiner is unable to determine the meaning as a matter specifying the claimed invention, the claim may be unclear.
- o However, in the case of a chemical compound with a limitation of use such as "for use as ..." (e.g., the chemical compound Z for use as Y), such limitation of use usually only indicates the utility of the chemical compound alone. Thus,

- o If a claim commences with such words as: "Apparatus for carrying out the process etc..." this must be construed as meaning merely "Apparatus suitable for carrying out the process". Similar considerations apply to claims directed to a product for a particular use, which are to be construed as meaning a substance or composition which is in fact suitable for the stated use.
- o In contrast to an apparatus or product claim, a claim commencing with such words as: "Method for achieving a particular effect" should not be interpreted as a statement that the process is merely suitable for achieving said effect, but rather as a functional feature concerning the process and, hence, defining one of the steps of the claimed

- o Claim languages such as "A product for...", "An apparatus for...", and "A method for..." are considered as part of the claim preamble. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. Catalina Mktg. Int'l v. Coolsavings.com, Inc., 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). If the body of a claim fully and intrinsically sets forth all of

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the claim should be construed to represent the chemical compound itself with no limitation of use (e.g., the chemical compound Z) without having to apply the approaches indicated in (1) and (2) below (see, Example 1) (court judgment for reference: Tokyo High Court Judgment of July 8, 1997 [1995 (Gyo Ke) No. 27]). This approach should be applied not only to chemical compounds but also to microorganisms. (Examination Guidelines Part II. Chapter 2. Section 1.5.2(2))

(1) General approach for the case where the claim includes a limitation of use

- o A limitation of use can be construed as a shape, structure, or composition (hereinafter simply referred to as a "structure, etc.") which is particularly suitable for such use, by considering the description, drawings and the common general technical knowledge as of the filing. As in such a case, where a product with a limitation of use is construed as a product which is particularly suitable for such use, the product should be construed as a product with the structure, etc. represented by the limitation of use.
- o Therefore, even when the matters specifying the claimed invention and the matters specifying a cited invention are the same in all respects except for the limitation of use, if the structure, etc. represented by the limitation of use differs, the two should be regarded as

method (see T 848/93, not published in the OJ).

- o Claims directed to the use of a process for a particular purpose are considered as claims to the process itself (T0684/02, not published in the OJ).

Products defined by their use in therapeutic and/or diagnostic methods ("medical use")

- o Art. 53(c) EPC prohibits that a European patent be granted for "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body". However, this prohibition does not extend to products for use in any of these methods, particularly substances or compositions, for which a patent may be obtained, subject to the general requirements for patentability.
- o Art. 54(4) and (5) were introduced in the EPC 2000 (in force since 13 December 2007, subject to transitional measures) in the first place to keep the legal status quo reached as a consequence of case law developments in this field (the so-called "Swiss type claims") and with the purpose of eliminating legal uncertainty on the patentability of further medical uses of known products.
- o New paragraphs (4) and (5) of Art. 54 EPC provide for an exception from the general principle that product claims can only be obtained for (absolutely) novel products. This, however, does not mean that product claims for the first and further medical

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. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

- o The court in *In re Sinex*, 135 USPQ 302, 305 (CCPA 1962) noted that statement of intended use in an apparatus claim did not distinguish over the prior art apparatus. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. An anticipation rejection was affirmed by the court in *In re Schreiber*, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) based on the factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner).
- o See MPEP 2111.02.

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- different inventions
- o On the other hand, if a product with a limitation of use cannot be construed as a product which is particularly suitable for such use even by considering the description, drawings and the common general technical knowledge as of the filing, such limitation of use is not construed as having a meaning that specifies the product except when it should be construed as representing a use invention set forth in (2) below.
 - o Therefore, in this case, if the matters specifying the claimed invention and the matters specifying a cited invention are the same in all respects except for the limitation of use, the two cannot be regarded as different inventions.

(Examination Guidelines Part II.
Chapter 2. Section 1.5.2(2))

(2) Approach for the case where an invention of product with a limitation of use should be construed as a use invention

- o Generally, a use invention is construed as an invention based on discovering an unknown attribute of a product and finding that the product is suitable for a new use due to the presence of such attribute.
- o When a claim includes a limitation of use and the claimed invention can be construed as an invention based on discovering an unknown attribute of a product and finding that the product is suitable for new use due to the presence of such attribute, the limitation of use should be

- uses need not fulfil all other requirements of patentability.
- o As a consequence, claims to known products for medical use (whether a "first medical use" within the meaning of Art. 54(4) EPC or a subsequent "specific use" within the meaning of Art. 54(5) EPC) must be in a form such as "Substance or composition X" followed by the indication of the use, for instance "... for use as a medicament", "... for use as an antibacterial agent " or "... for use in the treatment of disease Y".
 - o Use of method claims in the "Swiss-type" form, (e.g. second medical use claims of the type "use of product X for the manufacture of a medicament for the treatment of disease Y" or "Method for manufacturing a medicament intended for therapeutic application Y, characterised in that the substance X is used"), which were commonly used under the EPC 1973, are still allowable in parallel to the new claim format.
 - o Claims in the form "Use of substance or composition X for the treatment of disease Y..." will on the contrary still be interpreted as relating to a method for treatment explicitly excluded from patentability under Art. 53(c) EPC and therefore will not be accepted.

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regarded as having a meaning that specifies the claimed invention and it is appropriate to construe the claimed invention by including the aspect of the limitation of use. Therefore, in this case, even if the product itself is already known, the claimed invention can be novel as a use invention.

- o However, even when an unknown attribute has been discovered, if the claimed invention is not considered to provide new use for the product by considering the common general technical knowledge in the relevant technical field as of the filing, the claimed invention is regarded as lacking novelty. In addition, even when the claimed invention and a cited invention are inventions of products defined by different wordings in the limitation of use, the claimed invention is regarded as lacking novelty if the two cannot be distinguished in terms of their use by considering the common general technical knowledge in the relevant technical field as of the filing.

(Note 1) In general, when an unknown attribute of a product is discovered and an invention is found to be creative in respect to its use for a certain purpose that was unknown, such invention can be novel as a use invention. This approach to use invention is generally applied to technical fields in which it is relatively difficult to understand how to use the product from the structure or name of the product

- 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. In re Hack, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 197 USPQ 601, 607 (CCPA

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(e.g., the technical field of use of compositions containing chemical substances). On the other hand, the approach to use invention is not applied to machines, instruments, articles, and apparatuses because these products usually have fixed uses.

(Note 2) Even when the claimed invention provides a new use based on an attribute of the product, if a person skilled in the art could have easily arrived at such use based on known attributes or known product structures, the claimed invention is regarded as lacking an inventive step (Tokyo High Court Judgment of August 27, 2003 [2002 (Gyo Ke) No. 376]).

(Note 3) Looking at use inventions in respect to the statement in the claims, there are claims expressed by agent form, the method of use as well as those expressed by limitation of use. The guidelines mentioned above can also be applied to use inventions other than those expressed by limitation of use. However, due to the reason indicated in B.1.b., the applicable scope of the guidelines should be limited to the cases where any term that indicates use is included in the claims (e.g., "catalyst comprising ...," "ornamental material comprising an ... alloy" and "method of killing insects using ...").

(Examination Guidelines Part II.
Chapter 2. Section 1.5.2(2))

1978).
o See MPEP 2112.02.

c. Use claims

o "Use" is interpreted as a term meaning a method for using things

o Claims in a form such as "the use of a substance for achieving a

o A "use" claim is a claim that attempts to claim a process

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which is categorized into "process". For example, "Use of substance X as an insecticide" is construed as terms meaning "method for using substance X as an insecticide." "Use of substance X for the manufacture of a medicament for therapeutic application Y" is construed as terms meaning "method for using substance X for the manufacture of a medicament for therapeutic application Y."
(Examination Guidelines Part I. Chapter 1. Section 2.2.2.1(3))

certain effect" are understood as process claims for achieving said effect, and not as claims directed to the substance or device as intended for a certain use.

- o For example, a claim for "the use of substance X as an insecticide" should be regarded as equivalent to a "process" claim of the form "a process of killing insects using substance X". Thus a claim in the form indicated should not be interpreted as directed to the substance X recognisable (e.g. by further additives) as intended for use as an insecticide.
- o Similarly, a claim for "the use of a transistor in an amplifying circuit" would be equivalent to a process claim for the process of amplifying using a circuit containing the transistor and should not be interpreted as being directed to "an amplifying circuit in which the transistor is used", nor to "the process of using the transistor in building such a circuit".

without setting forth any steps involved in the process. Examples are "The use of a high carbon austenitic iron alloy having a proportion of free carbon as a vehicle brake part subject to stress by sliding friction" (Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967)) and "The use of a sustained release therapeutic agent in the body of ephedrine absorbed upon polystyrene sulfonic acid" (Clinical Products Ltd. v. Brenner, 149 USPQ 475 (D.D.C. 1966)). "Use" claims generally raise an issue of indefiniteness under 35 U.S.C. 112, second paragraph and may not be a proper process claim under 35 U.S.C. 101.

- o See MPEP 2173.05(q).

d. Product defined by the manufacturing process
(product-by-process claim)

- o Where a claim includes a statement defining a product by its manufacturing process, such a statement is construed as meaning a product itself unless it should be construed as different meaning in compliance with B.1.b. (Note) .
- o If an identical product can be obtained by a different process from the one stated in the claim, thus, the claimed invention is not novel where the product is publicly known prior to the filing.

- o Claims defining a product in terms of a process are to be construed as claims to the product as such, irrespective of whether the term "Product obtainable", "obtained", "directly obtained" or an equivalent wording is used in the product-by-process claim.
- o Such claims will then only be allowable if the product as such fulfils the requirements for patentability, i.e. inter alia that it is new and inventive.

- o A product-by-process claim is a product claim that defines the claimed product in terms of the process by which it is made. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made

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(Note) The reason of the above construction is that there are cases where a product cannot be defined by its structure but only can be defined by its manufacturing process (e.g., an invention of isolated protein) and that it is not appropriate to make a distinction between an invention defined by its structure and an invention defined by its manufacturing process. Thus, even though applicant's intention is clear to limit the claimed invention to only the product which is obtained by particular process, such as a claim reading as "Z which is obtained solely by process A," the claimed invention should be construed as the product itself.

(Examination Guidelines Part II. Chapter 2. Section 1.5.2(3))

by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

- o The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. In re Garner, 162 USPQ 221, 223 (CCPA 1979).
- o See also MPEP 2113 and 2173.05(p).

e. References to the description or drawings

o When a statement of a claim is made by a reference to the description or drawings, the scope of the invention maybe unclear as illustrated in example1, 2 below.

Example 1: A claim which includes such statement made by a reference as "an automatic drill machine as shown in Figure 1."

(It is not appropriate to refer to drawings because drawings generally have ambiguous meanings and could be construed in many ways.)

Example 2: A claim which includes statements made by a reference to a portion that cannot be clearly pointed out in the description or

o The definition of the invention should appear completely in the claim itself whenever this is reasonably practicable.

o The claims must not, in respect of the technical features of the invention, rely on references to the description or drawings "except where absolutely necessary". In particular they must not normally rely on such references as "as described in part ... of the description", or "as illustrated in Figure N of the drawings".

o The onus is upon the applicant to show that it is "absolutely necessary" to rely on references to the description or drawings in appropriate cases (see T 150/82, OJ 7/1984, 309). This may happen

o 37 CFR 1.58(a) states that "claims, may contain chemical and mathematical formulae, but shall not contain drawings or flow diagrams...Claims may contain tables either if necessary to conform to 35 U.S.C. 112 or if otherwise found to be desirable."

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

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drawings.

- o Note that, even by referring to the description or drawings, an invention can be stated clearly in a claim as in the following case.

Example: In an invention related to an alloy, there is a specific relation among components of the alloy and the relation can be defined by reference to the drawings as clearly as by a numerical or other literal expression.

"Heat-resisting Fe·Cr·Al alloy for electric-heating composed of Fe, Cr, Al within the scope circumscribed by points A(), B(), C(), and D() shown in the Figure 1 and impurities less than X%."

(Examination Guidelines Part I.
Chapter 1. Section 2.2.2.1(5))

if the invention involves some peculiar shape, illustrated in the drawings, which cannot be readily defined either in words or by a simple mathematical formula. Another special case is that in which the invention relates to chemical products some of whose features can be defined only by means of graphs or diagrams.

- o However, it should always be kept in mind that the manner in which a particular feature is depicted in the drawings may be accidental, in particular in schematic drawings. In such cases, the skilled person must be able to clearly and unmistakably recognise from the drawings, in the context of the whole description, that the feature as depicted is the deliberate result of the technical considerations directed to the solution of the technical problem involved.
- o A further special case is where the invention is characterised by parameters. Where the method of measurement is necessary for the unambiguous definition of a parameter, the method of and means for measurement of the parameter values need not be described in the claims if the description is so long that its inclusion would make the claim unclear or difficult to understand. In such cases the claim should include a reference to the description, in accordance with Rule 43(6) EPC.

applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

- o See MPEP 2173.05(s).

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C. Identification of the relevant state of the art

1. Definition of the state of the art

- o Article 29(1) of the Patent Act sets forth what constitutes prior art as follows:
 - (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.
 - o "Prior to the filing of the patent application" in the Article 29(1) of the Patent Act is different from "prior to the date of filing of a patent application". This means that the definite time even in hours and minutes of the filing be considered.
(Examination Guidelines Part II. Chapter 2. Section 1.2.1)
 - o Note that when the filing date of a patent application is the same as the date of the publication, the time of distribution is not deemed prior to the filing of a patent application, except when
- o Art. 54(1) EPC states that an invention is "considered to be new if it does not form part of the state of the art". The "state of the art" is defined Art. 54(2) EPC as "everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application".
 - o There are no restrictions whatsoever as to the geographical location where or the language or manner in which the relevant information was made available to the public. Nor is there any limit as to the age of the documents or other sources of information.
- o 35 U.S.C. 102 sets forth what constitutes prior art. See A.1. above. See also MPEP 901 to 901.04, 901.06, and 2121 to 2129.

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the filing time of application is clearly after the time of publication.
(Examination Guidelines Part II.
Chapter 2. Section 1.2.4(2))

2. Public availability of the state of the art

- o A "publicly known invention" of Article 29(1)(i) means an invention which have been known to an unspecified person without the duty of confidentiality.
 - o An invention, which is disclosed by a person assuming a duty of confidentiality to a third party without being aware of the secret, results in the "publicly known invention," despite the inventor's or the applicant's intent to keep it secret.
 - o For example, a manuscript for a journal of an academic society, in general, is usually kept secret against a third party, even after the receipt of the manuscript by the academic society. Therefore, the invention described in that manuscript is not considered a publicly known invention until its contents are released.
(Examination Guidelines Part II. Chapter 2. Section 1.2.2)
 - o A "publicly worked invention" of Article 29(1)(ii) means an invention which has been worked under the conditions where the contents of the invention are to be publicly known (Note 1) or can potentially be publicly known (Note 2) & (Note 3).
- (Note 1) "Conditions where the contents of the invention are to be publicly known" include, for

- o The relevant date for assessing public availability of the state of the art is the "date of filing of the European patent application", e.g., the earliest effective priority date. For the assessment of novelty, the minimum relevant unit of time is one day. Availability to the public "before the date of filing of the European patent application" is then to be understood as meaning "the previous day or earlier". Documents made available to the public the same day an application is filed, even if earlier in the day, shall not be considered.
- Availability to the public may result from:
- o Written description, i.e. a document, should be regarded as made available to the public if, at the relevant date, it was possible for members of the public to gain knowledge of the content of the document and there was no bar of confidentiality restricting the use or dissemination of such knowledge.
 - o Oral description. Facts which are unconditionally brought to the knowledge of members of the public in the course of a conversation or a lecture or by means of radio, television or

- o For U.S. patents and U.S. patent application publications, the date that the patent or patent application publication is made available to the public is the date it is available as a 35 U.S.C. 102(a) or (b) reference. For purposes of 35 U.S.C. 102(e), the effective U.S. filing date of the U.S. patent or U.S. patent application publication may be used as the prior art date. Note that the foreign priority date of the reference (U.S. patents and U.S. patent application publications) cannot be used as the 35 U.S.C. 102(e) date for prior art purposes. See 35 U.S.C. 102(e) and MPEP 2136.03, subsection I.
- o The date a foreign patent is effective as a reference under 35 U.S.C. 102(a) or (b) is usually the date patent rights are formally awarded to its applicant. In re Monks, 200 USPQ 129 (CCPA 1978). However, even if a patent grants an exclusionary right (is enforceable), it is not available as prior art under 35 U.S.C. 102(a) or (b) if it is secret or private. In re Carlson, 25 USPQ2d 1207, 1211 (Fed. Cir. 1992). The document must be at least minimally available to the public to constitute prior art. The patent is sufficiently

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example, a situation where a person skilled in the art may easily understand the contents of the invention by observing the manufacturing process associated with the invention at a plant that is exposed to an unspecified person.

(Note 2) "Conditions where the contents of the invention can potentially be publicly known" include, for example, a situation where, although inner parts of the manufacturing facility cannot be known to an unspecified person (a visiting inspector) by merely observing its exterior view and the person cannot know the invention as a whole without knowing that inner parts, the person is allowed to observe the inner parts or can have the inner parts explained. (i.e., the request for observation or explanation is not to be refused by the plant.)

(Note 3) When the working of the invention caused the fact that the invention is publicly known, the invention falls within a "publicly known invention" as stated in Patent Act Article 29(1)(i).

Thus, the Article 29(1)(ii) includes a situation where the invention publicly worked, even without the finding of the fact that an invention has become publicly known as a result of working.

(Examination Guidelines Part II. Chapter 2. Section 1.2.3)

- o A "publication" in the context of Article 29(1)(iii) is a document, a drawing or other similar medium

sound reproduction equipment (tapes and records) should be regarded as made available to the public. Although the EPC does not require a document reproducing the oral description, the EPO has adopted this practice.

- o In cases where only the oral description or lecture was publicly available before the "date of filing" of the European application, the document itself being published on or after this date, the subsequently published written description is deemed to give a true account of that oral description.
- o Prior use. Prior use may be constituted by producing, offering, marketing or otherwise exploiting a product, or by offering or marketing a process or its application or by applying the process. Marketing may be effected by sale or exchange.
- o As a matter of fact, prior use issues usually arise in post-grant proceedings. Subject-matter should be regarded as made available to the public by use if, at the relevant date, it was possible for members of the public to gain knowledge of the subject-matter and there was no bar of confidentiality restricting the use or dissemination of such knowledge.
- o "Any other way". The state of the art may also be made available to the public in other ways, as for example by demonstrating an object or process in specialist training courses or on television. Availability to the public in any other way includes all possibilities which

available to the public for the purposes of 35 U.S.C. 102(a) or (b) if it is laid open for public inspection or disseminated in printed form. A period of secrecy after granting the patent has been held to have no effect in connection with 35 U.S.C. 102(d). These patents are usable in rejections under 35 U.S.C. 102(d) as of the date patent rights are granted. In re Kathawala, 28 USPQ2d 1789 (Fed. Cir. 1993).

- o See MPEP 2126 and 2126.01.
- o A reference is a "printed publication" if it is accessible to the public. That is, the document has been disseminated or otherwise made available to the extent that persons interested and ordinary skilled in the subject matter or art, exercising reasonable diligence, can locate it. In re Wyer, 210 USPQ 790 (CCPA 1981).
- o A foreign application publication is considered as a "printed publication" and is available as prior art under 35 U.S.C. 102(a) or (b) when it is accessible to the public.
- o A doctoral thesis indexed and shelved in a library is sufficiently accessible to the public to constitute prior art as a "printed publication." In re Hall, 228 USPQ 453 (Fed. Cir. 1986). Even if access to the library is restricted, a reference will constitute a "printed publication" as long as a presumption is raised that the portion of the public concerned with the art would know of the invention. In re Bayer, 196 USPQ 670 (CCPA 1978).

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for the communication of information, duplicated for the purpose of disclosing the contents to the public through distribution.

- o A "Distribution" in the context of the wording "inventions described in a distributed publication" provided in Article 29(1)(iii) means the publication as defined above is placed in the condition where unspecified persons can read or see it. It does not necessitate the fact of a certain person's actual access to the publication.

(Examination Guidelines Part II.
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technological progress may subsequently offer of making available the aspect of the state of the art concerned.

- o A paper which is orally presented in a forum open to all interested persons constitutes a "printed publication" if written copies are disseminated without restriction. *Massachusetts Institute of Technology v. AB Fortia*, 227 USPQ 428, 432 (Fed. Cir. 1985).
- o Internal documents intended to be confidential are not "printed publications." In re *George*, 2 USPQ2d 1880 (Bd. Pat. App. & Inter. 1987).
- o A publicly displayed document where persons of ordinary skill in the art could see it and are not precluded from copying it can constitute a "printed publication," even if it is not disseminated by the distribution of reproductions or copies and/or indexed in a library or database. The "key inquiry is whether or not a reference has been made 'publicly accessible.'" In re *Klopfenstein*, 72 USPQ2d 1117, 1119 (Fed. Cir. 2004).
- o See MPEP 2128.01.
- o An electronic publication, including an on-line database or Internet publication, is considered to be a "printed publication" within the meaning of 35 U.S.C. 102(a) and (b) provided the publication was accessible to persons concerned with the art to which the document relates. In re *Wyer*, 210 USPQ 790, 795 (CCPA 1981). Prior art disclosures on the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted. Absent

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evidence of the date that the disclosure was publicly posted, if the publication itself does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b). However, it may be relied upon to provide evidence regarding the state of the art.

- o See MPEP 2128.
 - o An abandoned U.S. patent application becomes available as prior art only as of the date the public gains access to it. See 37 CFR 1.14(a)(1)(ii) and (iv). However, the subject matter of an abandoned U.S. patent application, including both provisional and nonprovisional applications, referred to in a prior art U.S. patent or U.S. patent application publication may be relied on in a 35 U.S.C. 102(e) rejection based on that U.S. patent or U.S. patent application publication if the disclosure of the abandoned application is actually included or incorporated by reference in the patent or patent application publication. See MPEP 2127, subsection I.
 - o Canceled matter in the application file of a U.S. patent cannot be relied upon in a rejection under 35 U.S.C. 102(e). Ex parte Stalego, 154 USPQ 52, 53 (Bd. App. 1966). The canceled matter only becomes available as prior art as of the date the application issues into a patent since this is the date the application file history becomes available to the public. In re Lund, 153 USPQ 625 (CCPA 1967).
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See MPEP 2127, subsection II.
o Figures that had been canceled from a Canadian patent application before issuance of the patent were available as prior art under 35 U.S.C. 102(b) as of the date the application became publicly accessible. *Bruckelmyer v. Ground Heaters, Inc.* 78 USPQ2d 1684 (Fed. Cir. 2006). See MPEP 2127, subsection II.

3. Drawings as prior art

o There is no special rule about the drawings as prior art (see C.6. below).

o Features shown solely in a drawing in a prior art document may be considered as forming part of the state of the art if the person skilled in that art is able, in the absence of any other description, to derive a technical teaching from them (T 204/83 OJ EPO 1985, 310).
o However, if the drawings are of a diagrammatic or schematic character - and this is the rule rather than the exception - they will not be taken into account for the assessment of novelty, unless the skilled person is able to clearly and unmistakably recognise from the drawings, in the context of the prior art disclosure, that the relevant feature as depicted is the deliberate result of the technical considerations described in that document.

o Drawings can be used as prior art. Drawings can anticipate claims if they clearly show the structure which is claimed. In re Mraz, 173 USPQ 25 (CCPA 1972). Drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. In re Aslanian, 200 USPQ 500 (CCPA 1979). When the reference does not disclose that the drawings are to scale and is silent as to dimensions, the drawings may not be relied on to show particular sizes. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000).
o See MPEP 2125.
o Drawings may be sufficiently enabling to put the public in the possession of the article shown by the drawings. Such an enabling drawing may be used to reject claims to the article. The prior art drawings must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). See MPEP 2121.04.

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4. Admissions as prior art

- o With regard to the novelty, there is no rule about admissions as prior art. Instead, the rule about applicant's admission is described in the "inventive step" section of the Examination Guidelines as follows:
- o If an applicant admits in the description that the 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))

- o Under the European "first-to-file" system, there is no provision whatsoever on whether an applicant's own admission that the work of another is prior art could be relied upon for anticipation, regardless of whether the admitted prior art would otherwise qualify as statutory prior art. For a prior art disclosure to be anticipatory, it must have been made available to the public at the effective priority date, e.g., it must be "statutory prior art".

- o Admissions by the applicant constitute prior art. A statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. Riverwood Int'l Corp. v. R.A. Jones & Co., 66 USPQ2d 1331, 1337 (Fed. Cir. 2003). However, even if labeled as "prior art," the work of the same inventive entity may not be considered as prior art against the claims unless it falls under one of the statutory categories of 35 U.S.C. 102. Consequently, the examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. In the absence of another credible explanation, examiners should treat such subject matter as the work of another.
- o See MPEP 2129.

5. Conflicting applications (earlier applications still unpublished at the critical date, other types of conflicting applications)

- o Article 29-2 of the Patent Act Where an invention claimed in a patent application is identical with an invention or device (excluding an invention or device made by the inventor of the invention claimed in the said patent application) disclosed in the description, scope of claims or drawings (in the case of the foreign language written application under Article 36-

- o Whether a published European application can be a conflicting application under Art. 54(3) EPC is determined firstly by its filing date and the date of its publication; the former must be before the filing or valid priority date of the application under examination, the latter must be on or after that date. Conflicting national prior rights are not comprised in prior art

- o All U.S. patent applications are preserved in confidence except for published applications, reissue applications, and applications in which a request to open the complete application to inspection by the public has been granted by the Office. See 35 U.S.C. 122(a) and 37 CFR 1.11(b) and 1.14(a). If an application that has not been published has an assignee or

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2(2), foreign language documents as provided in Article 36-2(1)) originally attached to the written application of another application for a patent or for a registration of a utility model which has been filed prior to the date of filing of the said patent application and published after the filing of the said patent application in the patent gazette under Article 66(3) of the Patent Act (hereinafter referred to as "gazette containing the patent") or in the utility model bulletin under Article 14(3) of the utility Model Act (Act No. 123 of 1959) (hereinafter referred to as "utility model bulletin") describing matters provided for in each of the paragraphs of the respective Article or for which the publication of the patent application has been effected, a patent shall not be granted for such an invention notwithstanding Article 29(1); provided, however, that this shall not apply where, at the time of the filing of the said patent application, the applicant of the said patent application and the applicant of the other application for a patent or for registration of a utility model are the same person.

o Article 39 of the Patent Act
(1) Where two or more patent applications claiming identical inventions have been filed on different dates, only the applicant who filed the patent application on the earliest date shall be entitled to obtain a patent for the invention claimed.

under Art. 54(3) EPC (T 550/88, OJ EPO 1992, 117).

- o As a general rule the search files will not be complete in respect of such material at the time the main search is made, and the Examiner will conduct a "topping-up" search upon entry in the examination phase and before starting assessment of novelty, to cover all European applications published up to eighteen months after the filing of the application under consideration.
- o If the conflicting published European application claims priority, the priority date replaces the filing date (Art. 89 EPC) for that subject-matter in the application which corresponds to the priority application.
- o If a priority claim was abandoned or otherwise lost with effect from a date prior to publication, the filing date and not the priority date is relevant, irrespective of whether or not the priority claim might have conferred a valid priority right.
- o Art. 54(3) EPC must be interpreted as referring to the publication of a "valid" application, i.e. a European patent application in existence at its publication date. It is in effect required that the conflicting application was still pending at its publication date (see J 5/81, OJ 4/1982, 155).
- o If the application was withdrawn or otherwise lost before the date of publication, but published because the preparations for

inventor in common with the application being examined, a rejection will be proper in some circumstances. For instance, when the claims between the two applications are not independent or distinct, a provisional nonstatutory double patenting rejection may be made.

- o A nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy and which is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinguishing from claims in a first patent. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 46 USPQ2d 1226 (Fed. Cir. 1998). See MPEP 804 for a discussion of nonstatutory double patenting rejection. If the copending applications differ by at least one inventor and at least one of the application is not patentable over the other, a provisional rejection under 35 U.S.C. 102(e) or 103 may be made when appropriate. See MPEP 2127, subsection IV., 706.02(f)(2), 706.02(k), 706.02(1)(1), and 706.02(1)(3).

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(2) Where two or more patent applications claiming identical inventions have been filed on the same date, only one applicant, who was selected by consultations between the applicants who filed the said applications, shall be entitled to obtain a patent for the invention claimed. Where no agreement is reached by consultations or consultations are unable to be held, none of the applicants shall be entitled to obtain a patent for the invention claimed.

(3) Where an invention and a device claimed in applications for a patent and a utility model registration are identical and the applications for a patent and a utility model registration are filed on different dates, the applicant for a patent may obtain a patent for the invention claimed therein, only if the application for a patent is filed prior to the application for a utility model registration.

(4) Where an invention and a device claimed in applications for a patent and a utility model registration are identical (excluding the case where an invention claimed in a patent application based on a utility model registration under Article 46-2(1) (including a patent application that is deemed to have been filed at the time of filing of the said patent application under Article 44(2) (including its *mutatis mutandis* application under Article 46(5)) and a device relating to the said utility model registration are identical) and the applications

publication had been completed, the publication has no effect under Art. 54(3) EPC, but only under Art. 54(2) EPC.

o The above principles also apply to PCT applications designating EP, but with an important restriction. Art. 153 EPC, in conjunction with Rule 165 EPC, makes it clear that a PCT application is not included in the state of the art for the purposes of 54(3) EPC, unless the PCT applicant has paid the required filing fee under Rule 159(1)(c) EPC and has supplied the PCT application to the EPO in English, French or German. Thus, a translation is required where the PCT application was published in Japanese, Chinese, Spanish, Russian or Arabic.

o There is no specific rule about European double patenting in the EPO. This is an indirect consequence of the regional dimension of the EPC. However, the EPO is currently considering whether the EPC as it stands could be used as a legal basis for introducing instructions for examiners explaining when and how to raise an objection of double patenting, and on which legal provisions.

o Once a European patent has been granted, it becomes a bundle of national patents, each of them falling under the relevant national provisions for any further action. Art 139 EPC, and in particular its paragraph 3, provides the legal framework for addressing possible double

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for a patent and a utility model registration are filed on the same date, only one of the applicants, selected by consultations between the applicants, shall be entitled to obtain a patent or a utility model registration. Where no agreement is reached by consultations or no consultations are able to be held, the applicant for a patent shall not be entitled to obtain a patent for the invention claimed therein.

(5) Where an application for a patent or a utility model registration has been waived, withdrawn or dismissed, or where the examiner's decision or trial decision to the effect that a patent application is to be refused has become final and binding, the application for a patent or a utility model registration shall, for the purpose of paragraphs (1) to (4), be deemed never to have been filed; provided, however, that this shall not apply to the case where the examiner's decision or trial decision to the effect that the patent application is to be refused has become final and binding on the basis that the latter sentence of paragraph (2) or (4) is applicable to the said patent application.

(6) An application for a patent or a utility model registration filed by a person who is neither the inventor nor designer nor the successor in title to the right to obtain a patent or a utility model registration shall, for the purpose of application of

patenting situations at the national level. Please note that national applications of one or more States designated in the European application of which the dates of filing are prior to the filing or priority date of the European application, and which were published as national applications or patents on or after that date, are not a bar to the grant of a European patent, but only a ground for revocation in the Contracting State(s) concerned.

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paragraphs (1) to (4), be deemed to be neither an application for a patent nor an application for a utility model registration.

(7) The Commissioner of the Patent Office shall, in the case of paragraph (2) or (4), order the applicant to hold consultations as specified under paragraph (2) or (4) and to report the result thereof, designating an adequate time limit.

(8) Where no report under the preceding paragraph is submitted within the time limited designated under the said paragraph, the Commissioner of the Patent Office may deem that no agreement under paragraph (2) or (4) has been reached.

6. Enabling disclosure of a prior art document

o Unless it is clear that an invention is described in a publication in such a manner that a person skilled in the art can make the product in case of a product invention or can use the process in case of a process invention in consideration of the common general knowledge as of the filing, the invention shall not be deemed to be "a cited invention" under Article 29(1)(iii).

o For example, if a chemical substance is expressed merely by its name or its chemical formula in a publication, and if it is not clear that a person skilled in the art can produce the chemical substance on the basis of the description in the publication, even in the light of the common general knowledge as of the filing, the chemical substance does not fall under "an

o Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1) EPC if the information given therein to the skilled person is sufficient to enable him, at the relevant date of the document, to practise the technical teaching which is the subject of the document, taking into account the general knowledge of the relevant technical field at that time (see T 26/85, OJ 1-2/1990, 22; T 206/83, OJ 1/1987, 5 and T 491/99, not published in the OJ).

o Similarly, it should be noted that a chemical compound, the name or formula of which is mentioned in a prior-art document, is not thereby considered as known unless the information in the document,

o When a reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on the applicant to provide facts rebutting the presumption of operability. In re Sasse, 207 USPQ 107 (CCPA 1980).

o A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." Impax Labs. Inc. v. Aventis Pharm. Inc., 81 USPQ2d 1001, 1013 (Fed.

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invention described in a publication" under Article 29(1)(iii). (Note that the above does not mean that the claim violates the enablement requirement under Article 36(4) where the publication is a patent application claiming the chemical substance as one of alternatives of Markush-type formula.)
(Examination Guidelines Part II. Chapter 2. Section 1.5.3(3))

together, where appropriate, with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.

- Cir. 2006).
- o The level of disclosure required within a reference to make it an "enabling disclosure" is the same no matter what type of prior art is at issue. It does not matter whether the prior art reference is a U.S. patent, foreign patent, a printed publication or other. In re Moreton, 129 USPQ 227 (CCPA 1961).
 - o See MPEP 2121.
 - o The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).
 - o A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 226 USPQ 619 (Fed. Cir. 1985).
 - o It is possible to make a 35 U.S.C. 102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., how to make or use the article disclosed. If the reference teaches every claimed element of the article, secondary evidence, such as other patents or

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publications, can be cited to show public possession of the method of making and/or using. In re Donohue, 226 USPQ 619, 621 (Fed. Cir. 1985).

- o See MPEP 2121.01 and 2131.01.
- o Where a process for making the compound is not developed until after the date of invention, the mere naming of a compound in a reference, without more, cannot constitute a description of the compound. In re Hoeksema, 158 USPQ 596 (CCPA 1968). Note, however, that a reference is presumed operable until applicant provides facts rebutting the presumption of operability. In re Sasse, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention. See MPEP 2121.02.

7. Establishing the relevant date of the prior art document

(1) When the time of publication is indicated in a publication, it is presumed as follows:

- (i) In the case where only the year of a publication is indicated, the last day of that year;
- (ii) In the case where a month and a year of a publication is indicated, the last day of the month of the year; and
- (iii) In the case where a day, a month and a year of a publication is indicated, that date.

(Examination Guidelines Part II. Chapter 2. Section 1.2.4(2))

(2) In the case where the date of publication is not indicated in a publication

- (i) In the case where the

- o By "relevant" date of a prior art document it is meant the publication date in the case of a previously published document and the date of filing (or priority date, where appropriate) in the case of a conflicting application according to Art. 54(3) EPC.
- o Where the date of publication of a prior art document is unclear, or where availability to the public might have occurred prior to that date, the examiner will try to find out whether the actual date of availability to the public can be established. Depending of the nature of the document, publishers, authoritative libraries such as the Library of Congress or the

- o See C.2. above regarding the relevant date of the prior art document. If the publication itself does not include a publication date (or retrieval date for documents on the Internet or on an on-line database), the publication cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b). However, the publication may be relied upon to provide evidence regarding the state of the art. Examiners may ask the Scientific and Technical Information Center to find the earliest date of publication or posting. See MPEP 2128 and 901.06(a), paragraph IV.G.

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distribution date of a foreign publication is unclear, but the date of its receipt in Japan is clear, the distribution date is presumed in the light of the period normally required to reach Japan from the country.

(ii) In the case where there is a derivative publication such as a book review, an extraction or a catalog, the distribution date of the publication in question is presumed based on the publication date of the derivative publication.

(iii) In the case where there is a second edition or a second print of the publication, the date of distribution is presumed to be the publication date of the first edition indicated therein.

() In the case where other appropriate information is available, the date of distribution is presumed or estimated therefrom.

(Examination Guidelines Part II.
Chapter 2. Section 1.2.4(2))

(3) In the case where the filing date of a patent application is the same as the date of the Publication

o In the case where the filing date of a patent application is the same as the date of the publication, the time of distribution is not deemed prior to the filing of a patent application, except when the filing time of application is clearly after the time of publication.

(Examination Guidelines Part II.
Chapter 2. Section 1.2.4(2))

British Library or universities might be contacted to this effect.

o Each piece of evidence is given an appropriate weight according to its probative value which is evaluated in view of the particular circumstances of each case, using the balance of probabilities as the standard of proof. According to this standard, it is not sufficient that the alleged fact is merely probable. The examiner must also be convinced that it is correct.

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8. Implicit/inherent features or well-known equivalents

- o An "invention described in a publication" means an invention identified by the matters described or essentially described, though not literally, in a publication.
"Matters essentially described, though not literally, in a publication" means those directly derivable from the matters described, by considering the common general knowledge (Note) as of the filing.
(Note) "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. Section 1.2.4(3))
- o Unless an invention can be identified by a person skilled in the art on the basis of the matters both described and essentially described, though not literally, in a publication, the invention shall not be deemed to be "an invention described in a publication," i.e., "a cited invention" under Article 29(1)(iii).
- o For example, where "matters described in a publication" are a part of alternatives of Markush-

- o Implicit features: A document takes away the novelty of any claimed subject-matter **derivable directly and unambiguously** from that document, including any features implicit to a person skilled in the art in what is expressly mentioned in the document. The implicit feature or characteristics must be immediately apparent to the person skilled in the art when reading the document. What matters is **not what might have been inherent** in what was made available to the public, **but what was actually made available to the public**.
- o Inherent/intrinsic features: As to availability of inherent or intrinsic features, e.g., whether a teaching in a prior art document also makes the inevitable result of carrying out such teaching available to the public, this is a question of fact, which must be decided in the context of each individual case.
- o Well-known equivalents: As to well-known equivalents, the limitation to subject-matter "derivable directly and unambiguously" from the prior art document for the assessment of novelty makes it very clear that it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the document. This is actually a matter of obviousness.

- o The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 (anticipation) or 103 (obviousness).
- o The court in *In re Crish*, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004) held the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."
- o See MPEP 2112, subsection I.
- o There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Shering Corp. v. Geneva Pharm. Inc.*, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency; see also *Toro Co. v. Deere & Co.*, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a

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type formula, it is determined whether a person skilled in the art can identify an invention of which a matter is one of the alternatives.

(Examination Guidelines Part II.
Chapter 2. Section 1.5.3(3))

characteristic is a necessary feature or result of a prior art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.). See MPEP 2112, subsection II.

o The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). See MPEP 2112, subsection IV.

o Once the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show that the prior art does not necessarily or inherently possess the characteristics of his [or her] claimed invention. See MPEP 2112, subsection V.

o Normally, only one reference

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should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to show that a characteristic not disclosed in the reference is inherent.

- o See MPEP 2131.01, subsection III.
- o Well-known equivalents are generally a consideration under the obviousness determination. However, under U.S. law, 35 U.S.C. 112, 6th paragraph permits an applicant to express a claim limitation in terms of a "means or step for performing a specified function without the recital of structure, material, or acts in support thereof." Such claim limitation "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. See MPEP 2181. If the examiner finds that a prior art element (1) performs the function specified in the claim, (2) is not excluded by any explicit definition provided in applicant's specification for an equivalent, and (3) is an equivalent of the means- (of step-) plus-function limitation, the examiner may rely on the prior art in an anticipation rejection under 35 U.S.C. 102. The burden then shifts to the applicant to show nonequivalence. See MPEP 2183.

9. Prior art expressed in specific or generic terms

(1) A cited invention expressed in a specific concept necessarily

o In considering novelty, it should be borne in mind that a generic

o If the prior art discloses a species falling within the

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(Generic disclosure and
specific examples)

implies or suggests "an invention of which matters are "the same family or the same genus, or have the common characteristic with the cited invention," and leads to the invention expressed in generic concept (Note 1). Without the cited invention expressed in specific concept being identified to its generic invention, the determination of whether the claimed generic invention is novel may be conducted at the comparison and determination steps.

(Examination Guidelines Part II. Chapter 2. Section 1.5.3(4))

(2) A cited invention expressed in generic concept neither implies nor suggests an invention expressed in a specific concept, and does not lead to the finding of the invention expressed in a specific concept (except when an invention expressed in a specific concept can be directly derivable from such a generic invention in consideration of the common general knowledge (Note 2)).

(Note 1) "Generic concepts" is defined as concepts integrating matters in the same family or the same genus, or a concept integrating a plurality of matters with the common characteristic.

(Note 2) The invention expressed in a specific concept isn't considered to be derived (disclosed) in the case where the generic concept merely contains the specific concept or the specific term can merely be listed from the generic term.

(Examination Guidelines Part II.

disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure.
o For example, a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper, and one of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets.

claimed genus, that prior art species will anticipate the claimed genus. In re Slayter, 125 USPQ 345, 347 (CCPA 1960).
o A generic chemical formula (prior art) will anticipate a claimed species covered by the formula when the species can be "at once envisaged" from the formula. If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 133 USPQ 275 (CCPA 1962).
o See MPEP 2131.02.

Chapter 2. Section 1.5.3(4))

10. Non-prejudicial disclosures

- o Article 30 of the Patent Act
 - (1) In the case of an invention which has fallen under any of the items of Article 29(1) by reason of the fact that the person having the right to obtain a patent has conducted a test, has made a presentation in a printed publication, has made a presentation through electric telecommunication lines, or has made a presentation in writing at a study meeting held by an academic group designated by the Commissioner of the Patent Office, such invention shall be deemed not have fallen under any of the items of Article 29(1) for the purposes of Article 29(1) and (2) for the invention claimed in a patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those items.
 - (2) In the case of an invention which has fallen under any of the items of Article 29(1) against the will of the person having the right to obtain a patent, the preceding paragraph shall also apply for the purposes of Article 29(1) and (2) to the invention claimed in the patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those paragraphs.
 - (3) In the case of an invention which has fallen under any of the items of Article 29(1) by reason of the fact that the person

- o Under Art. 55 EPC, there are two specific instances, and only two (described below), in which a prior disclosure of the invention is not taken into consideration as part of the state of the art.
 - o An essential condition, in both instances, is that for such a disclosure to be non-prejudicial, it must have taken place **earlier than six months preceding the filing of the application.**
 - o For calculating the six-month period, the relevant date is that of the actual filing date of the European patent application, not the priority date (G 3/98, OJ 2/2001, 62, and G 2/99, OJ 2/2001, 83).
- Oral descriptions by persons bound to secrecy, resulting from an "evident abuse"
- o The state of the art will not be affected by oral descriptions made by and to persons who were bound to, and preserved, secrecy, nor by an oral disclosure which was made no earlier than six months before the filing of the European patent application and which derives directly or indirectly from an evident abuse in relation to the applicant or his legal predecessor.
 - o For "evident abuse" to be established, there must be, on the part of the person disclosing the invention, either actual intent to cause harm or actual or constructive knowledge that harm would or could ensue from this disclosure (see T 585/92, OJ

- o Applicant's disclosure of his or her own work within the year before the U.S. application filing date cannot be used against him or her under 35 U.S.C. 102(a). See also MPEP 2132.01.
- o 35 U.S.C. 102(b) contains several distinct bars to patentability, each of which relates to activity or disclosure more than one year prior to the date of the application. They are - "public use" and "on sale." The policy underlying the public use and on-sale bars is to prevent the inventor from commercially exploiting the exclusivity of his [or her] invention substantially beyond the statutorily authorized period. RCA Corp. v. Data Gen. Corp., 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). Another policy underlying the public use and on-sale bars is to discourage "the removal of inventions from the public domain which the public justifiably comes to believe are freely available." See MPEP 2133.03.
- o If the use or sale was experimental, there is no bar under 35 U.S.C. 102(b). "A use or sale is experimental for purposes of section 102(b) if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose...If any commercial exploitation does occur, it must be merely incidental to the primary purpose

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having the right to obtain a patent has exhibited the invention at an exhibition held by the Government or a local public entity (hereinafter referred to as the "Government, etc."), an exhibition held by those who are not the Government, etc. where such exhibition has been designated by the Commissioner of the Patent Office, an international exhibition held in the territory of a country of the Union of the Paris Convention or a member of the World Trade Organization by its Government, etc. or those who are authorized thereby to hold such an exhibition, or an international exhibition held in the territory of a state which is neither of a country of the Union of the Paris Convention nor a member of the World Trade Organization by its Government, etc. or those who are authorized thereby where such exhibition has been designated by the Commissioner of the Patent Office, paragraph (1) shall also apply for the purposes of Article 29(1) and (2) to the invention claimed in the patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those items.

(4) Any person seeking the application of paragraph (1) or (3) shall submit to the Commissioner of the Patent Office, at the time of filing of the patent application, a document stating thereof and, within thirty days from the date of filing of the patent

3/1996, 129).

Display of the invention at an officially recognised international exhibition

- o The state of the art will not be affected by the display of the invention by the applicant or his legal predecessor at an officially recognised international exhibition as defined in Art. 55(1)(b) EPC if the corresponding application is filed within six months of the disclosure of the invention at the exhibition.
- o Furthermore, the applicant must state, at the time of filing the application, that the invention has been so displayed, and must also file a supporting certificate within four months, giving the particulars required by Rule 25 EPC. The list of the officially recognized international exhibitions is regularly updated in the Official Journal.

of the experimentation to perfect the invention." LaBounty Mfg. v. United States Int'l Trade Comm'n, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992). "The experimental use exception...does not include market testing where the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation." In re Smith, 218 USPQ 976, 983 (Fed. Cir. 1983).

- o Testing of an invention in the normal context of its technological development is generally within the realm of permitted experimental activity. Experimentation to determine product acceptance, i.e., market testing, is typical of a trader's and not an inventor's experiment and is thus not within the area of permitted experimental activity.
- o See MPEP 2133.03(e) to 2133.03(e)(7).

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application, a document proving the fact that the invention which has otherwise fallen under any of the items of Article 29(1) is an invention to which paragraph (1) or (3) of this Article may be applicable.

D. Assessment of novelty

1. Assessment approach of novelty

o The novelty requirement is applied to "claimed inventions." (Examination Guidelines Part II. Chapter 2. Section 1.3)
o The examiner shall determine whether or not a claimed invention is novel by judging whether the claimed invention falls under the inventions categorized in the provision of Article 29(1)(i) to (iii). When there are two or more claims in an application, the determination should be made for each claim. (Examination Guidelines Part II. Chapter 2. Section 1.4)

o Assessment of novelty involves a straightforward comparison of the technical features in the claim of the application under consideration against the technical features described in the prior art document under consideration. It will take into account the documents (if any) cited in the search report and any further document, such as those found in the topping up search or those introduced in the course of a proceedings in the EPO, unless the latter are held inadmissible for procedural reasons.
o The EPO may also invite the applicant to submit information on prior art which has been taken into consideration in national or regional patent proceedings concerning an invention to which the European patent application relates.
o Failure on the part of the applicant to comply with this invitation results in the application being deemed to be withdrawn under Art. 124(2) EPC.

o After the application has been read and the claimed invention understood, the examiner conducts a prior art search for the claimed invention. For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. See MPEP 706, 706.02 and 2131.

a. Comparison of a claimed invention with a prior art document

(1) The comparison between a claimed invention and a cited invention is conducted by finding of the identicalness and the

o Comparison of the claimed invention with a prior art document should be based on:
- the technical features in the

o To anticipate a claim, the reference must teach every element of the claim either expressly or inherently. The

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difference between the matters defining the claimed invention and the matters considered to be needed at the expression of the cited invention in words (hereinafter referred to as "matters defining the cited invention").

(Examination Guidelines Part II. Chapter 2. Section 1.5.4(1))

(2) A more specific concept within the concept of the claimed invention may be compared with a cited invention for the purpose of finding the identicalness and the difference between a claimed invention and a cited invention, instead of the method of comparison mentioned (1).

- o An example of "a more specific concept within the concept of a claimed invention" is the disclosed invention described in the description or the drawing as a mode for carrying out the claimed invention. The mode which is not disclosed in the description or the drawing may also be compared with the claimed invention as far as they are more specific concepts within the concept of the claimed invention.
- o This alternative method would be helpful for the examination of novelty in terms of claims with statements defining a product by its function or properties, etc., or claims with numerical limitation, etc.

(Examination Guidelines Part II. Chapter 2. Section 1.5.4(2))

(3) In cases where the matters defining a claimed invention is compared with the matters described in a cited publication instead of the method of

claims of the application under consideration, taken in their widest reasonable interpretation, and

- the technical features described in the prior art document under consideration, as they would have been understood by a person skilled in the art at the effective date of that prior art document.
- o Whether the problems addressed (or the objectives to be accomplished) in each case are similar or not is irrelevant to the assessment of novelty. What matters is whether the claimed features (or the claimed combination thereof) was already known in the prior art.
- o It is not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested in that document (T 305/87, OJ 8/1991, 429).

examiner determines what the claimed invention is by giving the claims the "broadest reasonable interpretation consistent with the specification" (see B.1. above). Once the examiner conducts a search and finds a printed publication or patent which discloses the claimed invention, the examiner should determine whether the rejection should be made under 35 U.S.C. 102(a), (b), or (e). In order to determine which section of 35 U.S.C. 102 applies, the effective filing date of the application must be determined and compared with the date of the reference.

- o The effective filing date of a U.S. application may be determined as follows:
 - (A) if the application is a continuation or divisional of one or more earlier U.S. applications or international applications and if the requirements of 35 U.S.C. 120 and 365(c), respectively, have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.
 - (B) if the application is a continuation-in-part of an earlier U.S. application or international application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application. Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have

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comparison mentioned (1), the finding of the identicalness and the difference between the claimed invention and the cited invention may be conducted in consideration of the common general knowledge as of the filing. But the result of using this method shall be the same as the result of the methods mentioned (1).
(Examination Guidelines Part II. Chapter 2. Section 1.5.4(3))

the effective filing date of that earlier parent application.
(C) if the application claims foreign priority under 35 U.S.C. 119(a)-(d) or 365(a) or (b), the effective filing date is the filing date of the U.S. application, unless (A) or (B) as set forth above applies. The filing date of the foreign priority document is not the effective filing date, although the filing date of the foreign priority document may be used to overcome certain references.
(D) if the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.
o See MPEP 706.02, subsection VI. See also MPEP 1893.03(b) for determining the effective filing date of a national stage application submitted under 35 U.S.C. 371.
o See MPEP 706.02(a) for determining the date of the reference.

b. Use of multiple prior art documents to show lack of novelty

The comparison shall not be conducted between a claimed invention and a combination of two or more cited inventions.
(Examination Guidelines Part II. Chapter 2. Section 1.5.4(4))

o It should be noted that in considering novelty (as distinct from inventive step), it is not permissible to combine separate items of prior art together.
o However, if a document (the "primary" document) refers explicitly to another document as providing more detailed information on certain features, the teaching of the latter is to

o Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:
(A) prove the primary reference contains an "enabled disclosure." In re Samour, 197 USPQ 1 (CCPA

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		<p>be regarded as incorporated into the document containing the reference, if the document referred to was available to the public on the publication date of the document containing the reference (see T 153/85, OJ 1-2/1988, 1).</p> <p>o In such cases, the relevant date for novelty purposes is always the date of the primary document. Furthermore, any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) as well as the prior art acknowledged in a document, insofar as explicitly described therein, are to be regarded as incorporated in the document.</p>	<p>1978);</p> <p>(B) explain the meaning of a term used in the primary reference. In re Baxter Travenol Labs., 21 USPQ2d 1281 (Fed. Cir. 1991); or</p> <p>(C) show that a characteristic not disclosed in the reference is inherent. Continental Can Co. USA v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).</p> <p>o See MPEP 2131.01.</p>
<p>c. <u>Showing of lack of novelty based on "public use" or "on sale"</u></p>	<p>o About the invention of "public use", see "publicly worked invention" mentioned in C.2.</p> <p>o About the invention of "on sale", there is no special rule in Japan.</p>	<p>o As already stated under C.2, prior use issues usually arise in post grant proceedings. Subject-matter should be regarded as made available to the public by use if, at the relevant date, it was possible for members of the public to gain knowledge of the subject-matter and there was no bar of confidentiality restricting the use or dissemination of such knowledge.</p> <p>o When dealing with an allegation that an object or process has been used in such a way that it is comprised in the state of the art, an Examiner will have to determine</p> <p>(i) the date on which the alleged use occurred, i.e. whether there was any instance of use before the relevant date (prior use);</p> <p>(ii) what has been used, in order to determine the degree of</p>	<p>o <u>35 U.S.C. 102(a)</u>:</p> <p>o 35 U.S.C. 102(a) states that "[a] person shall be entitled to a patent unless (a) the invention was known or used by others in this country...before the invention thereof by the applicant for a patent." The knowledge or use of 35 U.S.C. 102(a) must be knowledge or use which is accessible to the public. The knowledge or use is accessible to the public if there has been no deliberate attempt to keep it secret. W.L. Gore & Assoc. v. Garlock, Inc., 220 USPQ 303 (Fed. Cir. 1983). The knowledge or use in 35 U.S.C. 102(a) must be knowledge or use in this country. Prior knowledge or use which is not present in the United States, even if widespread in a foreign country, cannot be the basis of a rejection under 35 U.S.C. 102(a). In re Ekenstam, 118 USPQ 349</p>

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- similarity between the object used and the subject-matter of the European patent; and
- (iii) all the circumstances relating to the use, in order to determine whether and to what extent it was made available to the public, as for example the place of use and the form of use.
- o If an object is unconditionally sold to a member of the public, it should be regarded as made available to the public since the buyer thereby acquires unlimited possession of any knowledge which may be obtained from the object. Even where in such cases the specific features of the object may not be ascertained from an external examination, but only by further analysis, those features are nevertheless to be considered as having been made available to the public. This is irrespective of whether or not particular reasons can be identified for analysing the composition or internal structure of the object.
 - o However, this does not extend to extrinsic characteristics, e.g. features which are only revealed when the product is exposed to interaction with specifically chosen outside conditions in order to provide a particular effect or result or to discover potential results or capabilities, therefore pointing beyond the product per se as they are dependent on deliberate choices being made.
 - o If, on the other hand, an object could only be seen in a given place (a factory, for example) to
- (CCPA 1958).
- Prior knowledge or use under 35 U.S.C. 102(a) must be "by others," which refers to any entity which is different from the inventive entity of the application under examination. The entity need only differ by one person to be "by others." This holds true for all types of references eligible as prior art under 35 U.S.C. 102(a) including publications as well as public knowledge and use. Any other interpretation of 35 U.S.C. 102(a) "would negate the one year [grace] period afforded under § 102(b)." In re Katz, 215 USPQ 14 (CCPA 1982). See MPEP 2132.
- o 35 U.S.C. 102(b):
 - o 35 U.S.C. 102(b) states that "[a] person shall be entitled to a patent unless (b) the invention was...in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. 102(b) is applicable if the activity occurred more than 1 year prior to the effective filing date of the application. For the policy considerations underlying the public use and on-sale bars, see C.10 above.
 - o Public Use:
 - o The public use bar under 35 U.S.C. 102(b) arises where the invention is in public use more than one year before the effective filing date of the U.S. patent application and the invention is ready for patenting. Invitrogen Corp. v. Biocrest Manufacturing L.P., 76 USPQ2d
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which members of the public not bound to secrecy, including persons with sufficient technical knowledge to ascertain the specific features of the object, had access, all knowledge which an expert was able to gain from a purely external examination is to be regarded as having been made available to the public. In such cases, however, all concealed features which could be ascertained only by dismantling or destroying the object will not be deemed to have been made available to the public.

- o If there is an express or tacit agreement on secrecy, or if the circumstances of the case are such that such secrecy derives from a relationship of good faith or trust, the subject-matter disclosed in such circumstances will not be considered as having been made available to the public.
- o If the alleged prior use occurred on a "non-public property", for example in a factory, it will not be considered as use made available to the public, save in cases where the objects or processes used are exhibited, explained or shown to the public in such places, or where specialists not bound to secrecy are able to recognise their essential features from the outside.
- o However, the above-mentioned "non-public property" does not extend to the premises of a third party to whom the object in question was unconditionally sold or the place where the public

1741 (Fed. Cir. 2005). See C.10. above regarding the policy considerations underlying the public use and on-sale bars.

- o An inventor's private use of the invention, for his or her own enjoyment is not a public use. *Moleculon Research Corp. v. CBS, Inc.*, 229 USPQ 805, 809 Fed. Cir. 1986).
- o Where the inventor or someone connected to the inventor puts the invention on display or sells it, there is a "public use" within the meaning of 35 U.S.C. 102(b) even though by its very nature an invention is completely hidden from view as part of a larger machine or an article, if the invention is otherwise used in its natural and intended way and the larger machine or article is accessible to the public. In *re Blaisdell*, 113 USPQ 289, 292 (CCPA 1957).
- o "'Public use' of a claimed invention under 35 U.S.C. 102(b) occurs when the inventor allows another person to use the invention without limitation, restriction or obligation of secrecy to the inventor." In *re Smith*, 218 USPQ 976, 983 (Fed. Cir. 1983). The presence or absence of a confidentiality agreement is not itself determinative of the public use issue, but is one factor to be considered along with the time, place, and circumstances of the use which show the amount of control the inventor retained over the invention. *Moleculon Research Corp. v. CBS, Inc.*, 229 USPQ 805, 809 (Fed. Cir. 1986).
- o See MPEP 2133.03(a).

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could see the object in question
or ascertain features of it.

- o On sale:
- o The on-sale bar of 35 U.S.C. 102(b) occurs if there was a definite sale, or offer to sell, more than one year before the effective filing date of the U.S. patent application and the invention was ready for patenting. Pfaff v. Wells Elecs., Inc., 48 USPQ2d 1641, 1646-47 (1998).
- o An invention may be deemed to be "on sale" even though the sale was conditional. The fact that the sale is conditioned on buyer satisfaction does not, without more, prove that the sale was for experimental purpose. Strong v. General Elec. Co., 168 USPQ 8, 12 (5th Cir. 1970).
- o A "sale" need not be for profit to bar a patent. If the sale was for the commercial exploitation of the invention, it is "on sale" within the meaning of 35 U.S.C. 102(b). In re Dybel, 187 USPQ 593, 599 (CCPA 1975).
- o A single sale or offer to sell the invention may bar patentability under 35 U.S.C. 102(b). Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 94 (1876).
- o "[A]n assignment or sale of the rights in the invention and potential patent rights is not a sale of 'the invention' within the meaning of section 102(b)." Moleculon Research Corp. v. CBS, Inc., 229 USPQ 805, 809 (Fed. Cir. 1986).
- o Offer for sale:
- o "Only an offer which rises to the level of a commercial offer for sale, one which the other party

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could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)." Group One, Ltd. v. Hallmark Cards, Inc., 59 USPQ2d 1121, 1126 (Fed. Cir. 2001).

- o A rejected offer may create an on sale bar. UMC Elecs. v. United States, 2 USPQ2d 1465, 1469 (Fed. Cir. 1987).
- o See MPEP 2133.03(c).

o Experimental use:

- o If the use or sale was experimental, there is no bar under 35 U.S.C. 102(b). "A use or sale is experimental for purposes of section 102(b) if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose...If any commercial exploitation does occur, it must be merely incidental to the primary purpose of the experimentation to perfect the invention." LaBounty Mfg. v. United States Int'l Trade Comm'n, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992). "The experimental use exception...does not include market testing where the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation." In re Smith, 218 USPQ 976, 983 (Fed. Cir. 1983). See MPEP 2133.03(e) to 2133.03(e) (7).

d. Determining whether a claimed invention is novel

- o Where there is no difference between the matters defining a claimed invention and the matters

- o There is no specific definition of the person skilled in the art for the assessment of novelty. As

- o As noted in D.1. and D.1.a. above, to anticipate a claim, the reference must teach every

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defining a cited invention as a result of the comparison, the claimed invention is not novel. Where there is a difference, the claimed invention is novel. (Examination Guidelines Part II. Chapter 2. Section 1.5.5(1))

for the assessment of inventive step, 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.

- o 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 in the technical field concerned.
- o To this respect, personal knowledge of the Examiner, unsupported by documentary material or evidence of disclosure or use forming part of the state of the art, cannot of itself destroy the novelty of a claim (T 21/83, not published in the OJ).
- o It is the invention as claimed that is being examined for novelty. Thus, assessment of novelty is not limited to the embodiments of the invention explicitly described in the application.
- o Assessment of novelty amounts to a straightforward comparison of the technical features (or combination thereof) in the claim, taken in their widest reasonable interpretation, against the technical features (or combination thereof) in the prior art document under consideration, as they would have been understood by a person skilled in the art at the effective date of that prior art document.

element of the claim either expressly or inherently. See D.1.b. above regarding the use of multiple references in a 35 U.S.C. 102 rejection.

- o A reference may be relied upon for all that it contains. The court in *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed." See MPEP 2123.

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- o Whether the problems addressed in the prior art document and the claim are the same or not is absolutely irrelevant to the assessment of novelty. Only where a claim is directed to the use of an apparatus to perform a different function would an Examiner consider whether or not the claimed function is already known in the prior art.
- o Thus, **the problem-and-solution approach** used in the EPO for the assessment of inventive step **is not relevant for the assessment of novelty.**
- o The requirement of novelty under the EPC is a requirement of absolute novelty. However, this requirement does not apply to the so-called first and second or further medical uses of known products, which are, under Art. 54(4) and (5), subject to an exception from the general principle of absolute novelty (see below, under section D.2.a, under "Exception for claims to medical uses").

2. Assessment of the novelty of inventions claimed in specific forms of definition

a. The claim includes an expression specifying a product by its use

o See B.2.b. above.

o For claims directed to a physical entity, non-distinctive characteristics of a particular intended use should be disregarded. On the other hand, distinctive characteristics, even if not explicitly stated but merely implied by a particular use, should be taken into account.

o See B.2.b. above. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the

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- o Claims to the use of a known substance or composition may be held novel if the substance or composition as known in the prior art is in a form which would render it unsuitable for the stated use. However, if the known product is in a form in which it is in fact suitable for the stated use, though it has never been described for that use, it would deprive the claim of novelty.
- o Claims to the use of a known compound for a particular purpose (second non-medical use) which are based on a technical effect should be interpreted as including that technical effect as a functional technical feature and may be held novel if that technical feature has not previously been made available to the public (G 2/88, OJ 4/1990, 93, and G 6/88, OJ 4/1990, 114).
- o For example, a claim to a substance X for use as a catalyst would not be considered to be novel over the same substance known as a dye, unless the use referred to implies a particular form of the substance (e.g. the presence of certain additives) which distinguishes it from the known form of the substance.

Novelty exceptions for claims to medical uses

- o While methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are still excluded from patentability (now as statutory non-patentable subject-matter under new Art. 53(c) EPC),

- claim." Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). 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. Pitney Bowes, Inc. v. Hewlett-Packard Co., 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).
- o If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. An anticipation rejection was affirmed by the court in In re Schreiber, 44 USPQ2d 1429, 1431 (Fed. Cir 1997) based on the factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner).
- o See MPEP 2111.02.

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new or known products, in particular substances or compositions, for use in any of these methods (e.g., for "medical use") are not.

- o Art. 54(4) and (5) EPC as entered into force on 13 December 2007 provides for an exception from the general principle that product claims can only be obtained for (absolutely) novel products. Claims to a known substance or composition for its use in therapeutic and/or diagnostic methods ("medical use") may still be patentable if the claimed use is novel and inventive.
 - o According to Art. 54(4), a known substance or composition may only be patented for use in these methods if the known substance or composition was not previously disclosed for use in surgery, therapy or diagnostic methods practised on the human or animal body ("first medical use").
 - o Art. 54(5) EPC provides for the possibility to obtain a different purpose-related product protection for an invention relating to a second or further medical use of a substance already known to have been used in a "first medical use", provided that the second or further use is novel and inventive. It goes without saying that the scope of a claim to a second or further medical use will always be narrower than the claim to the first medical use.
 - o It should also be noted here that a mere pharmaceutical effect does not necessarily imply a therapeutic application. A
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defined, real treatment of a pathological condition is required for such a claim to be eligible for patentability.

- o If the condition to be treated is defined in functional terms, instructions in the form of experimental tests or testable criteria allowing the skilled person to recognise which conditions fall within the functional definition and accordingly within the scope of the claim must be available from the patent documents or from the common general knowledge (T 241/95, OJ 2/2001, 103).

b. Selection inventions

- o When an invention concerned fulfills all conditions (1)-(4) listed below, the invention is called "selected invention":
 - (1) The invention concerned pertains to a technical field in which an effect of a product is difficult to understand from its structure.
 - (2) An invention written in a publication (cited document) is expressed in either of the following:
 - (2-a) expressed in generic concept.
 - (2-b) expressed as alternatives either in form or de fact.
 - (3) The invention concerned is either of the following:
 - (3-a) expressed in more specific concept selected from the generic concept of (2-a).
 - (3-b) selected from a group of inventions each of which is identified by supposing that each of the alternatives of (2-b) is a matter to define each of such inventions

- o Selection inventions deal with the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned within a larger known set or range. In determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualized (concrete) form in the prior art (see T 12/81, OJ 8/1982, 296).

Selections from lists in a prior art document

A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then, under the "two-lists principle", the resulting combination of features confers novelty if it has not specifically disclosed in the prior art.

- o When the claimed compound is not specifically named in a reference, but instead it is necessary to select portions of teachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formulas to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once

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- (4) The invention concerned doesn't lack the novelty over the invention written in a publication.
- o Thus, an invention can be a selection invention, if the invention isn't considered to be an invention described in the publication (See, C.8.).
(Examination Guidelines Part II. Chapter 2. Section 2.5(3))
 - o "Alternatives in form" means a claim statement with an apparent form of alternatives. For example, a Markush practice claim or a multiple dependent claim which refers to two or more other claims in an alternative form.
 - o "Alternatives in de facto" means a claim statement which is of comprehensive nature but intends to include a certain number of more specific matters. Whether a claim statement is "de facto alternatives" should be determined in the light of the description, the drawings and the common general knowledge as of the filing in addition to the claim statement. For example, the claimed invention is "an alkyl with 1 to 10 carbons." (The above claim statement of comprehensive nature includes a methyl, an ethyl and so on.)
 - o As opposed to the above, a term "thermoplastic resin" in a claim should not be construed as one that merely denotes a certain number of more specified matters by means of the term of comprehensive nature except when the term is defined in the description and it should be construed as the "Alternatives in

Sub-ranges from a broader range in the prior art

- o A sub-range selected from a broader numerical range of the prior art is considered novel if each of the following three criteria is satisfied (see T 98/84, OJ 7/1985, 209; T 279/89, not published in the OJ):
 - (a) the selected sub-range is narrow compared to the known range
 - (b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range
 - (c) the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention (purposive selection, new technical teaching).
- o Whether a sub-range is "narrow" or "sufficiently far removed from" the range disclosed in the prior art has to be decided on a case-by-case basis.
- o A technical effect occurring in the claimed sub-range cannot in itself confer novelty on that sub-range, unless such technical effect occurs only in the selected sub-range, thus evidencing that the sub-range is not merely an arbitrary selection from the prior art. The new technical effect may also be the same effect as that attained with the broader known range, but to a significantly greater extent.

Overlapping ranges in the prior art and the claimed subject-matter

- o For the assessment of novelty of

envisaged." One may look at the preferred embodiments to determine which compounds can be anticipated. In re Petering, 133 USPQ 275 (CCPA 1962).

- o See MPEP 2131.02.
- o Anticipation of ranges:
 - o When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrower range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See e.g., *Atofina v. Great Lakes Chem. Corp*, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure

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de facto" in the light of the description, the drawings and the common general knowledge as of the filing.

- o Thus, the term should not be deemed to be de facto alternatives. In other words, it should be construed that the concept of "thermoplastic resin" includes uncertain number of more specified matters (e.g., polyethylene, polypropylene, etc.), and that the term denotes a certain generic concept in terms of characteristic which the more specific matters have in common (i.e., "thermoplasticity" in this case).

(Examination Guidelines Part II. Chapter 2. Section 1.5.5(2))

overlapping ranges, it has to be decided which subject-matter has been made available to the public by a prior art disclosure and thus forms part of the state of the art. In this context, not only examples, but the whole content of the prior art document should be taken into consideration.

- o Novelty will be destroyed by an explicitly mentioned end-point of the known range, explicitly mentioned intermediate values or a specific example of the prior art in the overlap. In addition, it must also be considered whether the skilled person, in the light of the technical facts and taking into account the general knowledge in the field to be expected from him, would have seriously contemplated applying the technical teaching of the prior art document in the range of overlap (see T 26/85, OJ 1-2/1990, 22; T 17/85, OJ 12/1986, 406; T 12/90, not published in the OJ ; T 536/95, not published in the OJ).

of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." Id. at 1424. Any evidence of unexpected results within the narrow range may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP 2131.03 and 2131.02.

c. The claim includes an expression specifying the function, properties, characteristics or mode of operation

(1) Where a claim includes statements defining a product by its function or properties, etc. and it falls under either the following (i) or (ii), there may be cases where it is difficult to compare of the claimed invention with a cited invention.

- o In the above cases, if the examiner has a reason to suspect that the claimed product would be prima facie identical with the product of the cited invention without making a strict comparison of the claimed product

- o Claims defining an "Apparatus for carrying out a certain process" will normally not be anticipated by apparatuses which otherwise possess all of the features specified in the claims but would be unsuitable for the stated purpose or would require further modification to enable them to be so used. Similar considerations apply to a claim for a product for a particular use.
- o For claims defining the invention, or a feature thereof, mainly by parameters, it may

- o See B.2.a above.
- o When the claimed product and the prior art product are identical in structure, a prima facie case of anticipation has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). See also Titanium Metals Corp. v. Banner, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and

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- with the product of the cited invention, the examiner may send the notice of reasons for refusal under Article 29(1) as far as there is no other difference.
- o 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 identical with the product of the cited invention.
 - o Where the applicant's argument, which is, for example, abstract or general, does not change the examiner's evaluation to that extent, the examiner makes a decision of refusal under Article 29(1).
 - o The above-mentioned handling, however, shall not be applied, if matters defining the cited invention fall under either the following (i) or (ii).
 - (i) a case where the function or properties, etc. is neither of the following:
 - the function or properties, etc. is standard;
 - the function or properties, etc. is commonly used by a person skilled in the art in the relevant technical field;
 - the function or properties, etc. is not commonly used but understandable of its relation to a commonly used function or characteristic, etc. for a person

- happen that in the relevant prior art a different parameter, or no parameter at all, is mentioned. If the known and the claimed products are identical in all other respects (which is to be expected if, for example, the starting products and the manufacturing processes are identical), then in the first place an objection of lack of novelty arises.
- o Cases in which unusual parameters are employed or a non-accessible apparatus for measuring the parameter(s) is used are prima facie objectionable on grounds of lack of clarity, as no meaningful comparison with the prior art can be made. However, such cases might also disguise a lack of novelty that must be duly taken into consideration by the Examiner.
 - o Claims directed to products defined by their mode of operation in the field of computer-related inventions are currently the subject of a referral to the Enlarged Board of Appeal (referenced under G 3/08; further information available on the EPO Internet Home Page).

0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

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- skilled in the art.
- (ii) a case where plural of the functions or properties, etc. is either of the following, but the combination of them as a whole falls under (i);
- the functions or properties, etc. is standard;
 - the functions or properties, etc. is commonly used by a person skilled in the art in the relevant technical field
 - the functions or properties, etc. is not commonly used but understandable of its relation to a commonly used function or characteristic, etc. for a person skilled in the art.

(Note) Function or properties, etc. should be deemed to be standard if it is either defined by JIS (Japanese Industrial Standards), ISO-standards (International Organization for Standardization-standards) or IEC-standards (International Electro-technical Commission-standards), or if it can be determined quantitatively by a method for testing or measuring which is provided in those standards. Function or characteristic, etc. should be deemed to be commonly used by a person skilled in the art if it is commonly used by a person skilled in the art in the technical field as well as its definition or the method for testing or measuring can be understood by a person skilled in the art.

(Examination Guidelines Part II.
Chapter 2. Section 1.5.5(3))

- (2) Examples where the examiner has a reason to suspect the prima

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- facie identity are the followings:
- o In the case when a prior art product is identical to the product of the claimed invention as a result of converting the function or characteristic, etc. into a different definition with the same meaning or a different method for testing or measuring the same;
 - o In the case when a claimed invention and a cited invention are defined by identical or similar function or properties, etc. which are measured or evaluated under different measuring conditions or different evaluation methods, and there is a certain relationship between them, and there is a high probability that the function or properties, etc. defining the cited invention is included in the function or properties, etc. defining the claimed invention, if measured or evaluated under the same measuring conditions or evaluation method as the claimed invention;
 - o In the case when a product of the claimed invention has been revealed identical in structure with a certain product after the filing and the product is publicly known prior to the filing;
 - o In the case when a prior art product which is identical or similar to a mode for carrying out the claimed invention (for example, a prior art product of which starting material is similar to and of which manufacturing process is identical to those of the mode
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- for carrying out the claimed invention, or (s)he discovers a prior art product of which starting material is identical with and of which manufacturing process is similar to those of the mode for carrying out the claimed invention, etc.); and
- o In the case when the claimed invention and a cited invention have common matters defining the inventions other than those defining a product by its function or properties, etc., and the cited invention has the same problem or effect as the matters defining a product by its function or properties, etc. have, and there is a high probability that the function or properties, etc. defining the cited invention is included in the function or characteristic, etc. defining the claimed invention
 - o The examiner should follow the ordinary method when the requirement of novelty can be examined without using this exceptional handling.
(Examination Guidelines Part II. Chapter 2. Section 1.5.5(3))

d. The claim defines a product by its manufacturing process (product-by-process claim)

- o Where a claim includes a statement defining a product by its manufacturing process, such a statement is construed as meaning a product itself unless it should be construed as different meaning in compliance with B.1.b.
- o If an identical product can be obtained by a different process from the one stated in the claim, thus, the claimed invention is not novel where the product is
 - o A claim defining a product in terms of a process is to be construed as a claim to the product as such. A product is not rendered novel merely by the fact that it is produced by means of a new process (see T 150/82, OJ 7/1984, 309). Thus, if the product is not novel, an objection of lack of novelty arises.
 - o See B.2.d. above.
 - o "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

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- publicly known prior to the filing(see B.2.d. above).
- 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 is the product itself structurally. In such circumstances, if the examiner has a reason to suspect that the claimed product would be prima facie identical to the product of the cited invention 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(1), as far as there is no other difference, as mentioned in the above D.2.c.
 - o The above-mentioned handling, however, shall not be applied, if matters defining the cited invention include statements defining a product by its manufacturing process.
(Examination Guidelines Part II.
Chapter 2. Section 1.5.5(4))
 - o Examples where the examiner has a reason to suspect the prima facie identity are the followings:
 - o In the case when a product of a cited invention of which starting material is similar to and of which manufacturing process is identical to those of the product of the claimed invention;
 - o In the case when a product of a cited invention of which starting material is identical with and of which manufacturing process is similar to those of product of the claimed invention;
 - o In the case when a product of the

though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

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claimed invention has been revealed identical in structure with a certain product after the filing, and the product is publicly known prior to the filing of the application; and

- o In the case when a cited invention which is identical with or similar to a mode for carrying out the claimed invention.

(Examination Guidelines Part II. Chapter 2. Section 1.5.5(4))

E. Examiner's holding of lack of novelty (e.g., rejection) and the applicant's reply to overcome the holding of lack of novelty

1. Examiner's holding of lack of novelty

- o If the examiner has a suspicion that a claimed invention is unpatentable under Article 29 (1), (s)he will send a notice of reasons for refusal to an applicant.
(Examination Guidelines Part II. Chapter 2. Section 1.6)
- o Reasons for refusal should be stated clearly and simply with points so as to make it easy for an applicant to understand.
- o For citation of prior art documents, the following matters should be noted;
 - (1) Cited documents should be specified and the cited parts required for comparison with the claimed invention and judgment should be specified.
 - (2) The technical contents found in the cited documents etc. should be clarified.
 - (3) Necessary and sufficient documents for constituting the reasons for refusal should be cited and too many documents

- o The Examiner's first communication under Art. 94(3) EPC will, as a general rule, cover all objections to the application. These objections may relate to formal matters and/or substantive matters. Substantive matters should normally be set out first.
- o For each objection the communication should indicate the part of the application which is deficient and the requirement of the EPC which is not met, either by referring to specific Articles or Rules, or by other clear indication.
- o It should also give the reason for any objection where this is not immediately apparent. For example, where prior art is cited and only part of a cited document is relevant, the particular passage relied upon should be identified.
- o The communication should be drafted in such a manner as to

- o 37 CFR 1.104(b) states that "[t]he 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." 37 CFR 1.104(c)(2) states that "[i]n 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."
- o The examiner should, as a part of the first Office action on the

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should not be cited unnecessarily.
(Examination Guidelines Part IX. Section 2, 4.2)

- o In principle, all of the reasons for refusal which have been found should be notified on the occasion of first notification of reasons for refusal. However, where it is clear that other reasons for refusal will be resolved if one reason for refusal is resolved, multiple reasons for refusal should not be always notified redundantly.
- o In drafting the first notification of reasons for refusal, the examiner should make an effort to notify the reasons for refusal required for the applicant to amend for obtaining the patent, without sticking to trivial matters.
(Examination Guidelines Part IX. Section 2, 4.3.1)

facilitate re-examination of the amended application and, in particular, to avoid the need for extensive re-reading.

- o The communication under Art. 94(3) EPC should include an invitation to the applicant to file his observations, to correct any deficiencies and, if necessary, to submit amendments to the description, claims and drawings. It must also state the period within which the applicant must reply.
- o Failure to respond to this communication within the time limit will result in the application being deemed withdrawn according to Art. 94(4) EPC.

merits, identify any claims which he or she judges, as presently recited, to be allowable and/or should suggest any way in which he or she considers that rejected claims may be amended to make them allowable. If the examiner does not do this, then by implication it will be understood by the applicant or his or her attorney or agent that in the examiner's opinion, as presently advised, there appears to be no allowable claim nor anything patentable in the subject matter to which the claims are directed. See MPEP 707.07(d).

2. Applicant's reply

- o The 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 invention is unpatentable under Article 29(1). Where the applicant's argument does not change the examiner's evaluation to that extent, the examiner makes a decision of refusal on the ground of lacking novelty.
(Examination Guidelines Part II.

- o The applicant may contest the finding of lack of novelty and/or file amendments with a view to overcome the objections raised by the Examiner.
- o The applicant files sound argumentation and/or evidence in support of his argument that the objection of lack of novelty does not hold.
- o If the applicant contests the public availability or assumed date of publication a prior art document or oral communication, the Examiner should consider whether to investigate the matter further.
- o If the applicant shows sound reasons for doubting whether the

- o 37 CFR 1.111(b) states that "[i]n order to be entitled to reconsideration or further examination, the applicant...must reply to the Office action. The reply by the applicant...must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references...A general allegation that the claims define

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Chapter 2. Section 1.6)

- document or the oral communication forms part of the "state of the art" in relation to his application, and any further investigation does not produce evidence sufficient to remove that doubt, the Examiner should not pursue the matter further.
- o If the contested prior art is prior use the Examiner may, depending on the circumstances, need to take further evidence for those facts which are relevant to the case and which cannot yet be considered proven on the basis of the evidence already submitted.
 - o Such evidence (e.g. hearing witnesses or performing an inspection) is usually offered in post-grant proceedings and is always taken under participation of all the parties concerned, normally in oral proceedings.

The applicant files amendments or auxiliary requests in order to overcome the novelty objection

- o In most of the cases, the applicant will file amendments to the claims, description and drawings, or even one or more subsidiary request(s) (the so-called "auxiliary requests", e.g. alternative sets of claims, with an amended description where appropriate).
- o For amendments or auxiliary requests to be considered, it must first be checked whether they meet the requirements of Art. 123 EPC (and Art. 76(1) EPC in case of a divisional application) before re-examination of novelty starts.

The applicant tries to restore

a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section."

- o MPEP 706.02(b) sets forth ways for overcoming a 35 U.S.C. 102 rejection based on a printed publication or a patent.
- o A rejection based on a printed publication or a patent under 35 U.S.C. 102(a) can be overcome by:
 - (A) persuasively arguing that the claims are patentably distinguishable from the prior art;
 - (B) amending the claims to patentably distinguish over the prior art;
 - (C) filing an affidavit or declaration under 37 CFR 1.131 showing prior invention, if the reference is not a U.S. patent or a U.S. patent application publication claiming the same patentable invention as defined in 37 CFR 41.203(a);
 - (D) filing an affidavit or declaration under 37 CFR 1.132 showing that the reference invention is not by "another;"
 - (E) perfecting a claim to priority under 35 U.S.C. 119(a)-(d); or
 - (F) perfecting benefit claim under 35 U.S.C. 119(e) or 120.

o A rejection based on a printed publication or a patent under 35 U.S.C. 102(b) can be overcome by:

- (A) persuasively arguing that the claims are patentably distinguishable from the prior art;

COMPARISON OF JPO, EPO & USPTO PATENT PRACTICE

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| <p><u>novelty over an accidental anticipation under Art. 54(2) EPC or a disclosure under Art. 54(3) EPC</u></p> <ul style="list-style-type: none">o Disclaimers not disclosed in the application as filed are normally not allowable under Art. 123(2). They may, however and as an exception to the rule, be allowed in a number of specific situations (see G 1/03, OJ 8-9/2004, 413, and G 2/03, OJ 8-9/2004, 448, and III, 4.20), such as - where lack of novelty is at stake - restoring novelty over a disclosure under Art. 54(3) EPC (conflicting applications) or over an accidental anticipation under Art. 54(2) EPC.o In both cases, the excluded prior art and the relation between the prior art and the disclaimer must also be indicated in the description, in accordance with Rule 42(1)(b) EPC.<ul style="list-style-type: none">(1) Restoring novelty over a disclosure under Art. 54(3) EPC:o Disclaimers not disclosed in the application as filed may be allowable to restore novelty over a disclosure under Art. 54(3) EPC, unless they would also restore novelty or render the claim inventive over a separate prior art document under Art. 54(2) EPC.<ul style="list-style-type: none">(2) Restoring novelty over an accidental anticipation under Art. 54(2) EPC:o An anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention. | <ul style="list-style-type: none">(B) amending the claims to patentably distinguish over the prior art;(C) perfecting benefit claim under 35 U.S.C. 120; or(D) perfecting benefit claim under 35 U.S.C. 119(e). <p>o <u>A rejection based on a printed publication or a patent under 35 U.S.C. 102(e) can be overcome by:</u></p> <ul style="list-style-type: none">(A) persuasively arguing that the claims are patentably distinguishable from the prior art;(B) amending the claims to patentably distinguish over the prior art;(C) filing an affidavit or declaration under 37 CFR 1.131 showing prior invention, if the reference is not a U.S. patent or a U.S. patent application publication claiming the same patentable invention as defined in 37 CFR 41.203(a);(D) filing an affidavit or declaration under 37 CFR 1.132 showing that the reference invention is not by "another;"(E) perfecting a claim to priority under 35 U.S.C. 119(a)-(d); or(F) perfecting benefit claim under 35 U.S.C. 119(e) or 120. |
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- o Thus, the status of "accidental" should be ascertained without looking at the available state of the art in the relevant field. In particular, a prior art anticipation does not become an "accidental" one merely because it is not the closest prior art (alternatively, because there are other more or less closely related disclosures).
 - o An accidental disclosure has actually nothing to do with the teaching of the claimed invention (e.g., it is not relevant for examining inventive step). By the same token, a disclaimer seeking to restore novelty over an accidental anticipation will not be allowed if it appears to be relevant for assessing inventive step.

 - o The applicant's reply does not (or not sufficiently) overcome the objections raised by the Examiner in its first communication:
 - o If re-examination shows that despite the applicant's submissions objections persist, and provided the applicant has been given the right to be heard under Art. 113(1) EPC (e.g., the decision is based solely on grounds on which he has had an opportunity to comment), the application is to be refused under Art 97(2) EPC (T 201/98, not published in OJ).
 - o In most cases, however, re-examination will show that there are good prospects of bringing the proceedings to a positive conclusion, i.e. in the form of a decision to grant. In such cases,
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if there are still objections to be met, the Examiner must consider whether they can best be resolved by a further written communication, a telephone discussion or a personal interview.

- o If substantial differences of opinion exist, the issues are generally best dealt with in writing. If, however, there seems to be confusion about points in dispute, e.g. the applicant seems to have misunderstood the Examiner's arguments or the applicant's own arguments are unclear, then an interview may be useful. If, on the other hand, the matters to be resolved are minor, they can be settled more expeditiously over the telephone.
 - o Interviews or telephone discussions do not constitute oral proceedings. The Examiner will, however, always record the particulars of an interview or telephone conversation.
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COMPARATIVE ANALYSIS

A. Judicial, legislative or administrative criteria or guidelines for determining novelty

1. Legislation (law and regulations)

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

2. Guidelines

See, A.2. in the comparative table.

See, also Appendix II.

3. Background and purpose of the provision relating to novelty

In the JPO and the EPO, novelty of the invention is required because an exclusive right of a patent is considered as a reward for the disclosure of the invention.

In the USPTO, in exchange for the rights granted by a patent, the claimed invention must satisfy the conditions for patentability and one of the conditions is that the claimed invention must be novel.

B. Determining the scope of the claimed invention

1. Basic principles of interpretation of claims

a. Wording of the claims

All three Offices interpret the claims based on the statement of the claims.

In the JPO and the EPO, the wordings of the claims are construed as what they normally mean.

In the USPTO, the claims must be interpreted as broadly as their terms reasonably allow. This means

that the words of a claim must be given their plain meaning unless the plain meaning is inconsistent with the specification.

There is no difference among the three Offices that interpretation of the wording of the claims is not limited to the embodiments.

b. Consideration of the description and drawings

All three Offices interpret the claims by considering the description and the drawings.

In the JPO, when terms or language used in the claim (matters defining the claimed invention) are defined or explained in the description or the drawings, the definition or explanation should be considered when the terms or language are construed.

In the EPO, the claims are interpreted with the help of the description and the drawings.

In the USPTO, the ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art".

2. Inventions claimed in specific forms of definition

a. Products defined by their function, properties, characteristics or mode of operation

In all three Offices, claims including expressions specifying a product by its function, properties, etc, are permitted.

In the JPO, when a claim includes an expression specifying a product by its function, properties, etc. , such an expression should, in principle, be construed as every product that has such function, properties, etc.

In the EPO, subject-matter defined by means of functional features in a claim is to be read in its broadest technically meaningful sense. If, however, the application taken as a whole conveys the impression that a function is to be carried out in a particular way, and the claim is formulated in such a way as to embrace other means or all means, of performing the function, an objection of lack of support will arise (Guidelines, C-III, 6.5.).

In the USPTO, there is nothing inherently wrong with defining some part of an invention in functional terms. When the claimed product and the prior art product are identical in structure, a prima facie case of anticipation has been established.

- b. Products or processes defined by their use for ... (e.g. "for use as ...", "apparatus for ...", "Method for ... ")

In the JPO, the limitation of the use is treated as follows:

(1) In the case of a chemical compound or micro organisms with a limitation of use such as "for use as ..." (e.g., the chemical compound Z for use as Y), such limitation of use usually only indicates the utility of the chemical compound alone. Thus, the claim should be construed to represent the chemical compound itself with no limitation of use (e.g., the chemical compound Z) without having to apply the approaches indicated in (2) and (3) below.

(2) In the case that the limitation of use is construed as a shape, structure, or composition

(hereinafter simply referred to as a "structure, etc.") which is particularly suitable for such use, by considering the description, drawings and the common general technical knowledge as of the filing. As in such a case, where a product with a limitation of use is construed as a product which is particularly suitable for such use, the product should be construed as a product with the structure, etc. represented by the limitation of use.

(3) In the case that a claim includes a limitation of use and the claimed invention can be construed as an invention based on discovering an unknown attribute of a product and finding that the product is suitable for new use due to the presence of such attribute, the limitation of use should be regarded as having a meaning that specifies the claimed invention and it is appropriate to construe the claimed invention by including the aspect of the limitation of use. Therefore, in this case, even if the product itself is already known, the claimed invention can be novel as a use invention.

In the EPO, the limitation of the use is treated as follows:

(1) In the case that a claim commences with such words as: "Apparatus for carrying out the process etc..." this must be construed as meaning merely "Apparatus suitable for carrying out the process". Similar considerations apply to claims directed to a product for a particular use, which are to be construed as meaning a substance or composition which is in fact suitable for the stated use. Claims to the use of a known substance or composition may be held novel if the substance or composition as known in the prior art is in a form which would render it unsuitable for the stated use (See, D.2.a. in the comparative table). However, if the known product is in a form in which it is in fact suitable for the stated use, though it has never been described for that use, it would deprive the claim of novelty.

(2) In the case that a claim commencing with such words as: "Method for achieving a particular effect" should not be interpreted as a statement that the process is merely suitable for achieving said effect, but rather as a functional feature concerning the process and, hence, defining one of

the steps of the claimed method.

(3) Regardless of the above (1), in the case of products defined by their use in therapeutic and/or diagnostic methods ("medical use"), the products with their use can be novel even though the products it self is known to the public as of the filing. Note that claims to known products for medical use (whether a "first medical use" within the meaning of Art. 54(4) EPC or a subsequent "specific use" within the meaning of Art. 54(5) EPC) must be in a form such as "Substance or composition X" followed by the indication of the use, for instance "... for use as a medicament", "... for use as an antibacterial agent " or "... for use in the treatment of disease Y".

In the USPTO, claim languages such as "A product for...", "An apparatus for...", and "A method for..." are considered as part of the claim preamble. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case. Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. On the other hand, if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states the purpose or intended use of the invention, the preamble is not considered a limitation and is of no significance to claim interpretation/construction.

Comparing the practice among three Offices, there is a big difference relating to a known product for new use. In the JPO, when the limitation of use is regarded as having a meaning that specifies the claimed invention, the invention can be novel even though the product itself is known. On the other hand, in the EPO such product is regarded not novel except for medical use. In the USPTO, such a product claim is also regarded as not novel. However, 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. When the claim recites using an old composition or structure and the "use" is

directed to a result or property of that composition or structure, then the claim is anticipated.
See MPEP 2112.02.

c. Use claims

All three Offices interpret the Use claims as the process claims.

In the JPO, "Use" is interpreted as a term meaning a method for using things which is categorized into "process".

In the EPO, claims in a form such as "the use of a substance for achieving a certain effect" are understood as process claims for achieving said effect, and not as claims directed to the substance or device as intended for a certain use.

In the USPTO, a "use" claim is considered as a claim that attempts to claim a process without setting forth any steps involved in the process. "Use" claims generally raise an issue of indefiniteness under 35 U.S.C. 112, second paragraph and may not be a proper process claim under 35 U.S.C. 101.

d. Product defined by the manufacturing process (product-by-process claim)

All three Offices interpret a claim which includes a statement defining a product by its manufacturing process as the product itself.

e. References to the description or drawings

In all three Offices, references to the description or drawings may not be allowed.

In the JPO, if a claim which includes references to the description or drawings is not clear as a result of the references, such claim is not allowed (see Article 36(6)(ii) of the Patent Act).

In the EPO, the claims must not, in respect of the technical features of the invention, rely on references to the description or drawings "except where absolutely necessary".

In the USPTO, 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.

C. Identification of the relevant state of the art

1. Definition of the state of the art

See, C.1. in the comparative table.

2. Public availability of the state of the art

There can be many forms that inventions are publically available, e.g. published in a document, described orally, etc (See, C.2. in the comparative table). However, the public availability of publications is compared here because most inventions cited in office actions as the prior art are described in publications.

In all three Offices, publications accessible to the public are regarded as made available to the public.

In the JPO, if a publication is placed in the condition where unspecified persons can read or see it, the publication is regarded as made available to the public. It does not necessitate the fact of a

certain person's actual access to the publication.

In the EPO, if a publication is possible for members of the public to gain knowledge of the content of the publication and there is no bar of confidentiality restricting the use or dissemination of such knowledge, the publication is regarded as made available to the public.

In the USPTO, if a publication has been disseminated or otherwise made available to the extent that persons interested and ordinary skilled in the subject matter or art, exercising reasonable diligence, can locate it, the publication is regarded as made available to the public.

3. Drawings as prior art

In all three Offices, drawings may be used as prior art.

In the JPO, there is no special rule about the drawings as prior art. However, if the drawings are disclosed to the extent that a person skilled in the art can carry out the invention (see, C.6.), the drawings may be used as prior art.

In the EPO, features shown solely in a drawing in a prior art document may be considered as forming part of the state of the art if the person skilled in that art is able, in the absence of any other description, to derive a technical teaching from them.

In the USPTO, drawings can be used as prior art and must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art.

4. Admissions as prior art

In the JPO and the EPO, there is no special rule about admissions as prior art.

In the USPTO, admissions by the applicant constitute prior art.

5. Conflicting applications (earlier applications still unpublished at the critical date, other types of conflicting applications)

All three Offices have rules relating to the conflicting applications. However, there are some differences among three Offices.

In the JPO, the Article 29-2 and 39 of the Paten Act relate to the conflicting applications.

(1)Article 29-2 states that where an invention claimed in a patent application is identical with an invention or device disclosed in the description, scope of claims or drawings originally attached to the written application of another application for a patent or for a registration of a utility model which has been filed prior to the date of filing of the said patent application and published after the filing of the said patent application, a patent shall not be granted for such an invention notwithstanding Article 29(1).

Note that Article 29-2 can't be applied when another application is made by the same applicant or inventor of the application concerned.

(2)On the other hand, Article 39 can be applied even though the applicants or inventors of both applications are same. However, Article 39 can't be applied unless claimed inventions of both applications are identical. These are because the aim of the Article 39 is to prevent double patenting.

(3)Note that, the concept of "identical" in Article 29-2 and 39 is broader than the concept of "lacking of novelty". Even though the matters defining a claimed invention is merely addition, deletion or replacement of well-known or commonly used art to a prior art, and there is no special effect compared

to the prior art, the claimed invention is considered to be identical ("essentially identical") and the claimed invention is deemed to be identical to the prior art, meanwhile, the such doesn't lacks the novelty usually.

In the EPO, whether a published European application can be a conflicting application under Art. 54(3) EPC is determined firstly by its filing date and the date of its publication; the former must be before the filing or valid priority date of the application under examination, the latter must be on or after that date. Conflicting national prior rights are not comprised in prior art under Art. 54(3) EPC.

In the USPTO, if an application that has not been published has an assignee or inventor in common with the application being examined, a rejection will be proper in some circumstances.

(1) If the copending applications differ by at least one inventor and at least one of the application is not patentable over the other, a provisional rejection under 35 U.S.C. 102(e) or 103 may be made when appropriate.

(2) When the claims between the two applications are not independent or distinct, a provisional double patenting rejection may be made.

Article 29-2 of the Patent Act in Japan and the 35 U.S.C. 102(e) or 103 are not applicable when inventors are same (See, (1) of the JPO and (1) of the USPTO). On the other hand, Article 39 of the Patent Act in Japan and Article 54(3) EPC are applicable when inventors or applicants are same.

The scope of the confliction is different among three Offices. In the EPO, the EPC 54(3) is a kind of the requirements of novelty. In the JPO, whether Article 29-2 and 39 of the Patent Act in Japan are applicable is a problem of the identicalness which is broader than novelty (See, (3) of the JPO). In the USPTO, the claims of the conflicting applications must be compared in determining whether a

provisional nonstatutory double patenting rejection should be made. A nonstatutory provisional double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by or would have been obvious, over the reference claim(s).

6. Enabling disclosure of a prior art document

In all three Offices, a prior art document must be disclosed to the extent that a person skilled in the art can enable the invention written in the document.

In the USPTO, when a reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on the applicant to provide facts rebutting the presumption of operability.

7. Establishing the relevant date of the prior art document

In the EPO and USPTO, the requirement of the novelty is examined based on the "date" (See, C.2. in the comparative table), meanwhile, in the JPO, the definite time even in hours and minutes is considered (See, C.1. in the comparative table). However, in the JPO, when the filing date of a patent application is the same as the date of the publication, the time of distribution is not deemed prior to the filing of a patent application, except when the filing time of application is clearly after the time of publication.

In the JPO, when the relevant date of the prior art document is not clear, the date is established as follows:

(1) When the time of publication is indicated in a publication, it is presumed as follows:

(i) In the case where only the year of a publication is indicated, the last day of that year;

- (ii) In the case where a month and a year of a publication is indicated, the last day of the month of the year; and
 - (iii) In the case where a day, a month and a year of a publication is indicated, that date.
- (2) In the case where the date of publication is not indicated in a publication
- (i) In the case where the distribution date of a foreign publication is unclear , but the date of its receipt in Japan is clear, the distribution date is presumed in the light of the period normally required to reach Japan from the country.
 - (ii) In the case where there is a derivative publication such as a book review, an extraction or a catalog, the distribution date of the publication in question is presumed based on the publication date of the derivative publication.
 - (iii) In the case where there is a second edition or a second print of the publication, the date of distribution is presumed to be the publication date of the first edition indicated therein.
 - () In the case where other appropriate information is available, the date of distribution is presumed or estimated therefrom.

In the EPO, where the date of publication of a prior art document is unclear, or where availability to the public might have occurred prior to that date, the examiner will try to find out whether the actual date of availability to the public can be established. Depending of the nature of the document, publishers, authoritative libraries such as the Library of Congress or the British Library or universities might be contacted to this effect. Each piece of evidence is given an appropriate weight according to its probative value which is evaluated in view of the particular circumstances of each case, using the balance of probabilities as the standard of proof. According to this standard, it is not sufficient that the alleged fact is merely probable. The examiner must also be convinced that it is correct.

In the USPTO, if the publication itself does not include a publication date (or retrieval date for documents on the Internet or on an on-line database), the publication cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b). However, the publication may be relied upon to provide evidence regarding the state of the art. Examiners may ask the Scientific and Technical Information Center to find the earliest date of publication or posting.

8. Implicit/inherent features or well-known equivalents

In the JPO, an "invention described in a publication" means an invention identified by the matters described or essentially described, though not literally, in a publication. Implicit/inherent features can be the matters essentially described.

On the other hand, replacement by the equivalents is considered as a matter of inventive step instead of a matter of novelty because the equivalents can not be regarded as described or essentially described even though they are well-known. Note that, relating to the Article 29-2 and 39 of the Patent Act (See, C.5.), the replacement by the equivalents can be involved in the scope of "identical" because the scope of identicalness of the Article 29-2 and 39 are broader than the scope of "invention described in a publication" of the Article 29(1).

In the EPO and the USPTO the requirement of novelty can be denied by Implicit/inherent features in a prior art. Meanwhile, the well-known equivalent is not considered as a matter of novelty but a matter of inventive step.

9. Prior art expressed in specific or generic terms (Generic disclosure and specific examples)

In all three Offices, a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure.

In the JPO, when an invention expressed in a specific concept can be directly derivable from a generic invention in consideration of the common general knowledge, the specific invention lacks the novelty. Note that the invention expressed in a specific concept isn't considered to be derived (disclosed) in the case where the generic concept merely contains the specific concept or the specific term can merely be listed from the generic term.

In the EPO, concerning the issue whether a generic disclosure take away the novelty of specific examples in special case, there is no established practice as to possible special cases, which are to be handled on a case by case basis.

In the USPTO, when an invention expressed in a specific concept can be "at once envisaged" from a generic invention, the specific invention lacks the novelty.

10. Non-prejudicial disclosures

All three Offices have rules relating to the Non-prejudicial disclosures. However, their scopes and requirements are different each other.

In the JPO, following disclosures can be treated as non-prejudicial disclosures within six months from the date on which the invention first fell under any of the items of Article 29(1) of the Patent Act.

- (1) When the person having the right to obtain a patent has conducted a test, has made a presentation in a printed publication, has made a presentation through electric telecommunication lines, or has made a presentation in writing at a study meeting held by an academic group designated by the Commissioner of the Patent Office.
- (2) When the invention is disclosed against the will of the person having the right to obtain a patent.

(3) When the person having the right to obtain a patent has exhibited the invention at an exhibition held by the Government or a local public entity (hereinafter referred to as the "Government, etc."), an exhibition held by those who are not the Government, etc. where such exhibition has been designated by the Commissioner of the Patent Office, an international exhibition held in the territory of a country of the Union of the Paris Convention or a member of the World Trade Organization by its Government, etc. or those who are authorized thereby to hold such an exhibition, or an international exhibition held in the territory of a state which is neither of a country of the Union of the Paris Convention nor a member of the World Trade Organization by its Government, etc. or those who are authorized thereby where such exhibition has been designated by the Commissioner of the Patent Office.

In the case of (1) and (3), Applicants shall submit to the Commissioner of the Patent Office, at the time of filing of the patent application, a document stating thereof and, within thirty days from the date of filing of the patent application, a document proving the fact that the invention which has otherwise fallen under any of the items of Article 29(1) is an invention to which Article 30(1) or (3) of this Article may be applicable.

In the EPO, the rules relating to the Non-prejudicial disclosures can be applicable only for the following disclosures within six months.

- (1) Oral descriptions by persons bound to secrecy, resulting from an "evident abuse".
- (2) Display of the invention at an officially recognized international exhibition.

In the USPTO, applicant's disclosure of his or her own work within the year before the U.S. application filing date cannot be used against him or her under 35 U.S.C. 102(a). 35 U.S.C. 102(b) contains several distinct bars to patentability, each of which relates to activity or disclosure more than one year prior to the date of the application. Note that if the use or sale was experimental, there is no bar

under 35 U.S.C. 102(b).

D. Assessment of novelty

1. Assessment approach of novelty

In the all three Offices, the novelty requirement is applied to claimed inventions.

a. Comparison of a claimed invention with a prior art document

All three Offices compare a claimed invention and an invention written in a prior art document.

In the JPO, the comparison between a claimed invention and a cited invention is conducted by finding of the identicalness and the difference between the matters defining the claimed invention and the matters considered to be needed at the expression of the cited invention in words.

In the EPO, assessment of novelty amounts to a straightforward comparison of the technical features (or combination thereof) in the claim, taken in their widest reasonable interpretation, against the technical features (or combination thereof) in the prior art document under consideration, as they would have been understood by a person skilled in the art at the effective date of that prior art document (See, D.1.d. in the comparative table).

In the USPTO, the examiner determines what the claimed invention is by giving the claims the "broadest reasonable interpretation consistent with the specification" (see B.1. above). Once the examiner conducts a search and finds a printed publication or patent which discloses the claimed invention, the examiner should determine whether the rejection should be made under 35 U.S.C. 102(a), (b), or (e). In order to determine which section of 35 U.S.C. 102 applies, the effective filing date of the application must be determined and compared with the date of the reference.

b. Use of multiple prior art documents to show lack of novelty

In the all three Offices, to use a combination of multiple cited inventions to show lack of novelty is generally not permitted.

In the EPO, however, if a document (the "primary" document) refers explicitly to another document as providing more detailed information on certain features, the teaching of the latter is to be regarded as incorporated into the document containing the reference, if the document referred to was available to the public on the publication date of the document containing the reference.

In the USPTO, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to prove the primary reference contains an "enabled disclosure.", explain the meaning of a term used in the primary reference or show that a characteristic not disclosed in the reference is inherent.

c. Showing of lack of novelty based on "public use" or "on sale"

In the JPO and the EPO, there is no special rule with regard to "public use" or "on sale" (See C.2.).

On the other hand, in the USPTO, 35 U.S.C. 102(b) states that "[a] person shall be entitled to a patent unless (b) the invention was...in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(1) Public use

The public use bar under 35 U.S.C. 102(b) arises where the invention is in public use more than one year before the effective filing date of the U.S. patent application and the invention is ready for patenting. An inventor's private use of the invention, for his or her own enjoyment is not a public

use. Where the inventor or someone connected to the inventor puts the invention on display or sells it, there is a "public use" within the meaning of 35 U.S.C. 102(b) even though by its very nature an invention is completely hidden from view as part of a larger machine or an article, if the invention is otherwise used in its natural and intended way and the larger machine or article is accessible to the public.

(2) On sale

The on-sale bar of 35 U.S.C. 102(b) occurs if there was a definite sale, or offer to sell, more than one year before the effective filing date of the U.S. patent application and the invention was ready for patenting. An invention may be deemed to be "on sale" even though the sale was conditional. The fact that the sale is conditioned on buyer satisfaction does not, without more, prove that the sale was for experimental purpose. A "sale" need not be for profit to bar a patent. If the sale was for the commercial exploitation of the invention, it is "on sale" within the meaning of 35 U.S.C. 102(b). A single sale or offer to sell the invention may bar patentability under 35 U.S.C. 102(b). "[A]n assignment or sale of the rights in the invention and potential patent rights is not a sale of 'the invention' within the meaning of section 102(b)."

(3) Offer for sale

"Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under 102(b)." A rejected offer may create an on sale bar.

(4) Experimental use

If the use or sale was experimental, there is no bar under 35 U.S.C. 102(b). "A use or sale is experimental for purposes of section 102(b) if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose...If any commercial exploitation does occur, it must be merely incidental to the primary purpose of the experimentation to perfect the invention.". "The experimental use exception...does not include market testing where

the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation."

d. Determining whether a claimed invention is novel

In the JPO, Where there is no difference between the matters defining a claimed invention and the matters defining a cited invention as a result of the comparison, the claimed invention is not novel. Where there is a difference, the claimed invention is novel.

In the EPO, the requirement of novelty under the EPC is a requirement of absolute novelty. However, this requirement does not apply to the so-called first and second or further medical uses of known products, which are, under Art. 54(4) and (5), subject to an exception from the general principle of absolute novelty (see below, under section D.2.a, under "Exception for claims to medical uses").

Whether the problems addressed in the prior art document and the claim are the same or not is absolutely irrelevant to the assessment of novelty. Only where a claim is directed to the use of an apparatus to perform a different function would an Examiner consider whether or not the claimed function is already known in the prior art. Thus, the problem-and-solution approach used in the EPO for the assessment of inventive step is not relevant for the assessment of novelty.

In the USPTO, to anticipate a claim, the reference must teach every element of the claim either expressly or inherently. A reference may be relied upon for all that it contains. The prior art anticipated the claims even though it taught away from the claimed invention.

2. Assessment of the novelty of inventions claimed in specific forms of definition

a. The claim includes an expression specifying a product by its use

See, B.2.b.

b. Selection inventions

In all three Offices, whether the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned within a larger known set or range is novel can be an issue.

In the JPO, if an invention isn't considered to be an invention described in the publication, the invention can be novel. When the invention cannot be identified by a person skilled in the art on the basis of the matters both described and essentially described, though not literally, in a publication, the invention isn't considered to be an invention described in the publication (See, C.8. in the comparative table).

In the EPO, in determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualized (concrete) form in the prior art.

(1) Selections from lists in a prior art document

A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then, under the "two-lists principle", the resulting combination of features confers novelty if it has not specifically disclosed in the prior art.

(2) Sub-ranges from a broader range in the prior art

A sub-range selected from a broader numerical range of the prior art is considered novel if each of the following three criteria is satisfied:

(a) the selected sub-range is narrow compared to the known range

(b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range

(c) the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention (purposive selection, new technical teaching).

(3) Overlapping ranges in the prior art and the claimed subject-matter

For the assessment of novelty of overlapping ranges, it has to be decided which subject-matter has been made available to the public by a prior art disclosure and thus forms part of the state of the art. In this context, not only examples, but the whole content of the prior art document should be taken into consideration. Novelty will be destroyed by an explicitly mentioned endpoint of the known range, explicitly mentioned intermediate values or a specific example of the prior art in the overlap.

In addition, it must also be considered whether the skilled person, in the light of the technical facts and taking into account the general knowledge in the field to be expected from him, would have seriously contemplated applying the technical teaching of the prior art document in the range of overlap.

In the USPTO, in determining the novelty of a selection invention is as follows:

(1) Anticipation of selection from generic chemical formula

When the claimed compound is not specifically named in a reference, but instead it is necessary to select portions of teachings within the reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formulas to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of

the compounds can be "at once envisaged." One may look at the preferred embodiments to determine which compounds can be anticipated.

(2) Anticipation of ranges

When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrower range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching.

The expressions of rules in each three Offices are different. However the basic concept is common in all three Offices. That is, in order to take over the novelty of an invention, only disclosing abstract set or range in prior art isn't sufficient and more concrete disclosure is necessary in some kind.

c. The claim includes an expression specifying the function, properties, characteristics or mode of operation

When a claim includes an expression specifying the function, properties, characteristics or mode of operation, it can be hard to compare strictly the claimed invention with prior art. In all three Offices, if the claimed invention seems not to be novel over the prior art, the examiner can still establish a prima facie case of lack of novelty.

In the JPO, when a claim falls under the following (i) or (ii) and the examiner has a reason to suspect that the claimed product would be prima facie identical with the product of the cited invention 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(1) as far as there is no other difference.

(i) a case where the function or properties, etc. is neither of the following:

- the function or properties, etc. is standard;
- the function or properties, etc. is commonly used by a person skilled in the art in the relevant technical field;
- the function or properties, etc. is not commonly used but understandable of its relation to a commonly used function or characteristic, etc. for a person skilled in the art.

(ii) a case where plural of the functions or properties, etc. is either of the following, but the combination of them as a whole falls under (i);

- the functions or properties, etc. is standard;
- the functions or properties, etc. is commonly used by a person skilled in the art in the relevant technical field
- the functions or properties, etc. is not commonly used but understandable of its relation to a commonly used function or characteristic, etc. for a person skilled in the art.

In the EPO, for claims defining the invention, or a feature thereof, mainly by parameters, it may happen that in the relevant prior art a different parameter, or no parameter at all, is mentioned. If the known and the claimed products are identical in all other respects (which is to be expected if, for example, the starting products and the manufacturing processes are identical), then in the first place an objection of lack of novelty arises.

In the USPTO, when the claimed product and the prior art product are identical in structure, a prima facie case of anticipation has been established.

d. The claim defines a product by its manufacturing process (product-by-process claim)

All three Offices interpret a claim which includes a statement defining a product by its manufacturing process as the product itself. Thus, if the product itself is known to the public, the claimed invention lacks the novelty.

E. Examiner's holding of lack of novelty (e.g., rejection) and the applicant's reply to overcome the holding of lack of novelty

1. Examiner's holding of lack of novelty

See, E.1. in the comparative table.

2. Applicant's reply

See, E.2. in the comparative table.

Appendix I-1 - Articles concerning the novelty in the Japanese Patent Act

Article 29 (1) of the Patent Act

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.

Article 29-2 of the Patent Act

Where an invention claimed in a patent application is identical with an invention or device (excluding an invention or device made by the inventor of the invention claimed in the said patent application) disclosed in the description, scope of claims or drawings (in the case of the foreign language written application under Article 36-2(2), foreign language documents as provided in Article 36-2(1)) originally attached to the written application of another application for a patent or for a registration of a utility model which has been filed prior to the date of filing of the said patent application and published after the filing of the said patent application in the patent gazette under Article 66(3) of the Patent Act (hereinafter referred to as "gazette containing the patent") or in the utility model bulletin under Article 14(3) of the utility Model Act (Act No. 123 of 1959) (hereinafter referred to as "utility model bulletin") describing matters provided for in each of the paragraphs of the respective Article or for which the publication of the patent application has been effected, a

patent shall not be granted for such an invention notwithstanding Article 29(1); provided, however, that this shall not apply where, at the time of the filing of the said patent application, the applicant of the said patent application and the applicant of the other application for a patent or for registration of a utility model are the same person.

Article 30 of the Patent Act

- (1) In the case of an invention which has fallen under any of the items of Article 29(1) by reason of the fact that the person having the right to obtain a patent has conducted a test, has made a presentation in a printed publication, has made a presentation through electric telecommunication lines, or has made a presentation in writing at a study meeting held by an academic group designated by the Commissioner of the Patent Office, such invention shall be deemed not have fallen under any of the items of Article 29(1) for the purposes of Article 29(1) and (2) for the invention claimed in a patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those items.
- (2) In the case of an invention which has fallen under any of the items of Article 29(1) against the will of the person having the right to obtain a patent, the preceding paragraph shall also apply for the purposes of Article 29(1) and (2) to the invention claimed in the patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those paragraphs.
- (3) In the case of an invention which has fallen under any of the items of Article 29(1) by reason of the fact that the person having the right to obtain a patent has exhibited the invention at an exhibition held by the Government or a local public entity (hereinafter referred to as the "Government, etc."), an exhibition held by those who are not the Government, etc. where such exhibition has been designated by the Commissioner of the Patent Office, an international exhibition held in the territory of a country of the Union of the Paris Convention or a member of the World

Trade Organization by its Government, etc. or those who are authorized thereby to hold such an exhibition, or an international exhibition held in the territory of a state which is neither of a country of the Union of the Paris Convention nor a member of the World Trade Organization by its Government, etc. or those who are authorized thereby where such exhibition has been designated by the Commissioner of the Patent Office, paragraph (1) shall also apply for the purposes of Article 29(1) and (2) to the invention claimed in the patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those items.

- (4) Any person seeking the application of paragraph (1) or (3) shall submit to the Commissioner of the Patent Office, at the time of filing of the patent application, a document stating thereof and, within thirty days from the date of filing of the patent application, a document proving the fact that the invention which has otherwise fallen under any of the items of Article 29(1) is an invention to which paragraph (1) or (3) of this Article may be applicable.

Article 39 of the Patent Act

- (1) Where two or more patent applications claiming identical inventions have been filed on different dates, only the applicant who filed the patent application on the earliest date shall be entitled to obtain a patent for the invention claimed.
- (2) Where two or more patent applications claiming identical inventions have been filed on the same date, only one applicant, who was selected by consultations between the applicants who filed the said applications, shall be entitled to obtain a patent for the invention claimed. Where no agreement is reached by consultations or consultations are unable to be held, none of the applicants shall be entitled to obtain a patent for the invention claimed.
- (3) Where an invention and a device claimed in applications for a patent and a utility model registration are identical and the applications for a patent and a utility model registration are filed on different dates, the applicant for a patent may obtain a patent for the invention claimed

therein, only if the application for a patent is filed prior to the application for a utility model registration.

- (4) Where an invention and a device claimed in applications for a patent and a utility model registration are identical (excluding the case where an invention claimed in a patent application based on a utility model registration under Article 46-2(1) (including a patent application that is deemed to have been filed at the time of filing of the said patent application under Article 44(2) (including its mutatis mutandis application under Article 46(5)) and a device relating to the said utility model registration are identical) and the applications for a patent and a utility model registration are filed on the same date, only one of the applicants, selected by consultations between the applicants, shall be entitled to obtain a patent or a utility model registration. Where no agreement is reached by consultations or no consultations are able to be held, the applicant for a patent shall not be entitled to obtain a patent for the invention claimed therein.
- (5) Where an application for a patent or a utility model registration has been waived, withdrawn or dismissed, or where the examiner's decision or trial decision to the effect that a patent application is to be refused has become final and binding, the application for a patent or a utility model registration shall, for the purpose of paragraphs (1) to (4), be deemed never to have been filed; provided, however, that this shall not apply to the case where the examiner's decision or trial decision to the effect that the patent application is to be refused has become final and binding on the basis that the latter sentence of paragraph (2) or (4) is applicable to the said patent application.
- (6) An application for a patent or a utility model registration filed by a person who is neither the inventor nor designer nor the successor in title to the right to obtain a patent or a utility model registration shall, for the purpose of application of paragraphs (1) to (4), be deemed to be neither an application for a patent nor an application for a utility model registration.
- (7) The Commissioner of the Patent Office shall, in the case of paragraph (2) or (4), order the

applicant to hold consultations as specified under paragraph (2) or (4) and to report the result thereof, designating an adequate time limit.

(8) Where no report under the preceding paragraph is submitted within the time limited designated under the said paragraph, the Commissioner of the Patent Office may deem that no agreement under paragraph (2) or (4) has been reached.

Further information about the Japanese Patent Act can be obtained from Japanese Law Translation.

<http://www.japaneselawtranslation.go.jp/>

Appendix I-2 - Articles concerning the novelty of the European Patent Convention (EPC)

Article 54 EPC - Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

Article 55 EPC - Non-prejudicial disclosures

(1) For the application of Article 54, a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of:

(a) an evident abuse in relation to the applicant or his legal predecessor, or

(b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.

(2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application, that the invention has been so displayed and files a supporting certificate within the time limit and under the conditions laid down in the Implementing Regulations.

Article 139 - Prior rights and rights arising on the same date

(NB: Article 139 EPC does not bar the grant of a European patent. It merely sets a ground for revocation in the EPC Contracting States)

(1) In any designated Contracting State a European patent application and a European patent shall have with regard to a national patent application and a national patent the same prior right effect as a national patent application and a national patent.

(2) A national patent application and a national patent in a Contracting State shall have with regard to a European patent designating that Contracting State the same prior right effect as if the European patent were a national patent.

(3) Any Contracting State may prescribe whether and on what terms an invention disclosed in both a European patent application or patent and a national application or patent having the same date of filing or, where priority is claimed, the same date of priority, may be protected simultaneously by both applications or patents.

Further information about the EPC can be obtained from the EPO website.

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

Appendix I-3 - A Section concerning the novelty of the 35 U.S.C.

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention

by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such

person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Further information about the 35 U.S.C. can be obtained from the USPTO website.

<http://www.uspto.gov/web/patents/legis.htm>

Appendix II - Examination Guidelines of Trilateral Offices

JPO (Japanese)

http://www.jpo.go.jp/shiryoku/kijun/kijun2/tukujitu_kijun.htm

JPO (English Draft Translation)

http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm

EPO

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

USPTO

<http://www.uspto.gov/web/offices/pac/mpep/index.htm>