COMPARATIVE STUDY REPORT

ON

TRILATERAL PROJECT 12.6

REQUIREMENTS FOR DISCLOSURE AND CLAIMS

CONTENTS

COMPARISON OUTLINE

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
1. Legal bases concerning the requirements for disclosure and claims			
(1) Relevant provisions in laws and implementing regulations	o Patent Act Article 36 (Patent Applications)	o The provisions of the new European Patent Convention (EPC) (as published in the EPO Official Journal (2007), Special Edition 1, entry into force on 13.12.2007 at the latest) which are particularly relevant to the requirements for disclosure and claims are the following: Article 78(1) EPC: Requirements of the European patent application Article 80 EPC: Date of filing Article 83 EPC: Disclosure of the invention Article 84 EPC: The claims Article 85 EPC: The abstract Article 123 EPC: Amendments	o The relevant sections of U.S. patent law that form the foundation for the disclosure and the claims are Title 35 of the United States Code Section 112 (35 U.S.C. 112) and Section 113 (35 U.S.C. 113). In USPTO practice, the disclosure includes the specification, which includes the description and the claims; and the drawings. 35 U.S.C. 112 Specification. In USPTO practice, there is a separate statutory requirement for drawings that is set forth in 35 U.S.C. 113. 35 U.S.C. 113. Drawings.

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o Regulations under the Patent Act Article 24 (Form of specification) Form 29 Article 24-2 (Detailed description of the invention) Article 24-3 (Description of claims) Article 24-4 (Form of claims) Form 29-2 Article 25 (Form of drawing) Form 30 Article 25-2 (Description of abstract) Article 25-3 (Form of abstract) Form 31	o Rules 40 and 41 Minimum requirements to be fulfilled for according a date of filing (see also Rule 56 for missing parts of the description and missing drawings "completely contained" in a claimed priority document) Rules 42 to 43 and 46 to 49 EPC: Provisions governing the application Rule 137: Amendment of the European patent application Rule 138: Correction of errors	o The relevant implementing regulations are Sections 1.71- 1.75, 1.77, 1.81 and 1.83 of Title 37 of the Code of Federal Regulations (37 CFR 1.71- 1.75, 1.77, 1.81 and 1.83), which are as follows: Section 1.71 Detailed description and specification of the invention. Section 1.72 Title and abstract. Section 1.73 Summary of the invention. Section 1.74 Reference to drawings. Section 1.75 Claim(s) Section 1.77

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			Arrangement of application elements.
			Section 1.81 Drawings required in patent application. Section 1.83 Content of drawing.
(2)Examination guidelines, manuals, standards, etc.			
	o Examination Guidelines Part I SPECIFICATION	o The Guidelines for examination in the European Patent Office (hereinafter "Guidelines") (Guidelines to the new version of the Convention, December 2007) deal with the requirements for disclosure and claims particularly in the following sections: Guidelines concerning Article 83 (disclosure) are to be found in C-II, 4.1.4.3 , 4.9, 4.10, 4.11, 4.17, 4.19, , 6.1 and 6.3. Guidelines concerning Article 84 (claims) are to be found in C-III, 1 , 3.7, 4.1 to 4.22 , 5 , 6.1 to 6.6.	o USPTO practice relating to the requirements for disclosure and claims is set forth in various sections of the Manual of Patent Examining Procedure (MPEP), such as Sections 201, 608, 706 and 904.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		Other requirements to be met by the description are dealt with in C-II, 4.2 to 4.8, 4.12 to 4.19 , 6 and 7, and C-III, 4.3, 4.4, 4.10, 4.11, 4.17 to 4.19, 6 and 8, C-IV, 6.3 and 8. . For amendments see C-VI, 4.6 to 5.3.11, 5.5 and for correction C-VI, 3.1, 5.4 , A-II, 5 and A-X, 11.2.1. Other requirements to be met by the claims are dealt with in C-III 2 to 6, C-VI, 3.1 A-X, 11.2.2, B XII, 2.2 Guidelines relating to the drawings are given in A-II, 5,A-X; B.12, 2.1; C-II, 5; C-VI, 3.1, and regarding the abstract in A-III, 10; B-IV, 1, 4; B-X, 7, B-XI and Annex, and C-II, 2.	
(3) Background and purpose of the statutory requirements for disclosure	o The object of Patent System is to encourage inventions by promoting their protection and utilization so as to contribute to the development of industry. (Article 1 of the Patent Act)	o The disclosure of the invention to the public is regarded as the counterpart for the temporary monopoly granted in return by the public authorities to the applicant. o The public must always be able to carry out	o To obtain a patent on a new, useful, and nonobvious product or process, the inventor must file with his/her application a specification fully disclosing the invention and how to make and use it.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		the invention from the disclosure. The statutory requirements for the disclosure are intended to ensure this, even after the monopoly has expired. o As the claims determine the ambit of the patent, interpretation as to their exact scope may be necessary at several stages in the life of the application and the patent. This interpretation is carried out with the help of the description and any drawings. Furthermore, a quick grasp of the disclosure is easier if the latter has a standardized structure of specific elements. This is an important factor in facilitating search and examination.	o The requirement of adequate disclosure assures that the public receives a "quid pro quo" for the patent granted to the inventor. o Full disclosure of the invention and the manner of making and using it on publication of the patent application/issuance of the patent immediately increases the storehouse of public information available for further research and innovation and assures that the invention will be freely available to all once the statutory period of patent expires.

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o The Patent System promotes protection of inventions by granting a patent right or exclusive right under certain conditions for a certain period of time to those who have developed and disclosed new technology, while it gives the public an opportunity to gain access to the invention by disclosing technical details of the invention. The protection and utilization of an invention as described above are promoted through a patent specification and drawings which serve both as a technical document disclosing technical details of an invention and as a document of title defining the technical scope of a patented invention accurately.	o Therefore certain formal and substantive requirements must be fulfilled not only by the claims but also by the description and any drawings. o One task of the examiner is to check compliance with these requirements in order to be able to carry out a proper substantive examination thus facilitating the task of the judge in any litigation, ensuring legal security for the patent proprietor and his competitors and increasing the value of patent information available to the public.	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	Requirements for description of the "detailed description of the invention" in a specification are provided under Patent Act Article 36(4), and requirements for description of the claims are provided under Patent Act Article 36(5) and 36(6). Only a specification that meets these requirements serves both as a technical document and as a document of title. (Examination Guidelines Part I Chapter 1. Section 1.)		
2. Description of the invention			

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(1) Matters to be stated in the description and their arrangement	o In the specification, 1. the title of the invention, 2. a brief explanation of the drawings (if drawings are accompanied) 3. a detailed description of the invention, shall be stated. (Article 36(3) of the Patent Act, Form 29) o The detailed description of the invention shall be described in such a manner that a person skilled in the art to which the invention pertains can carry out the claimed invention. (Article 36(4)(i) of the Patent Act)	o Articles 78, 80 and 83 form the basis for requiring a description, while the content and form of the description is governed by Rule 42. o The order of presentation of the various sections set out in Rule 42 (1) need not be strictly adhered to, where a different order is more helpful (Rule 42(2)). For example, in the course of the detailed description of carrying out the invention, references to prior art related to a particular item involved in carrying out the invention are allowed. o No titles or headings are required for the individual sections referred to in Rule 42 (1)If such headings are included, they may stand but should preferably be deleted. o Rule 42 states (1) The description shall: (a) specify the technical field to which the invention relates;	o The required matters to be included in the disclosure and their arrangement is USPTO practice are set forth in 37 CFR 1.77 and MPEP 608.01(a). MPEP 608.01(a) states in part: o The following order of arrangement is preferable, but not mandatory in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated. (a) Title of the Invention. (b) Cross-References to Related Applications. (c) Statement Regarding Federally Sponsored Research or Development. (d) The names of the parties to a joint research agreement. (e) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on a compact disc and an incorporation-by-reference of the material on the compact disc (see 37 CFR 1.52(e)(5)). The total

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o The detailed description of the invention shall state, in principle, “Technical Field”, “Background Art”, “Problem to be Solved by the Invention”, “Means for Solving a Technical Problem”, “Effect of the Invention”, “the Best Mode for Carrying out the Invention”, “Working Example”, “Industrial Applicability” is indicated in this order. (Form 29)	(b) indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and examine the European patent application , and, preferably, cite the documents reflecting such art; (c) disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such and its solution can be understood, and state any advantageous effects of the invention with reference to the background art:	number of compact discs including duplicates and the files on each compact disc must be specified. (f) Background of the Invention. (1) Field of the invention. (2) Description of the related art including information disclosed under 37 CFR 1.97 and1.98. (g) Brief Summary of the Invention. (h) Brief Description of the Several View of the Drawings. (i) Detailed Description of the Invention. (j) Claim or Claims. (k) Abstract of the Disclosure. (l) "Sequence Listing," if on paper (see 37 CFR 1.821-1.825).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		(d) briefly describe the figures in the drawings, if any; (e) describe in detail at least one way of carrying out the invention claimed using examples where appropriate and referring to the drawings, if any; (f) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry. (2) The description shall be presented in the manner and order specified in paragraph 1, unless because of the nature of the invention, a different presentation would afford a better understanding or be more concise.	

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(2) Title of the invention	o The "Title of the Invention" should be such as to indicate concisely the invention concerned. (Form 29)	o The requirement that the title of the invention be taken from the Request for grant and restated at the beginning of the description has been deleted.	o The title of the invention should be brief but technically accurate and descriptive, and should contain fewer than 500 characters. However, brevity will be sacrificed to gain informative value for indexing, classifying, searching, etc. (MPEP 606 and 606.01).
(3) Explanation of the invention			
(i) Technical field, industrial field of utilization	o As “Technical Field to which an Invention Pertains”, at least one technical field to which a claimed invention pertains should be stated in a specification. o However, the “Technical Field to which an Invention Pertains” is not required to be explicitly stated if a person skilled in the art can understand it without such explicit statements when looking into overall descriptions in the specification and drawings taking into consideration the common general knowledge as of the filing. This is because strictly applying the requirement to such a case would rather result in redundant descriptions.	o A general indication of the technical field (here taken to be synonymous with industrial field of utilisation) is required under Rule 42 (1) (a). o one practical effect should be to inform the reader as succinctly as possible as to whether it is of interest to read further.	o In USPTO practice, the field of the invention is recited in the background of the invention. o The applicable guideline is set forth in MPEP 608.01(c) (1), which states: 608.01(c) Background of the Invention (1) Field of the Invention: A statement of the field of the art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions. The statement should be directed to the subject matter of the claimed invention.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o Further, in cases where an invention is deemed not to pertain to existing technical fields like an invention developed based on an entirely new conception which is completely different from prior art, an application for such an invention need not to state existing technical fields, and statements of the new technical field developed by the invention suffices the requirement. (Examination Guidelines Part I Chapter 1. Section 3.3.2(1)①)		
(ii) Prior art, background art	o The detailed description of the invention shall provide the source of the information concerning the invention(s) known to the public through publication such as the name of the publication and others where the person requesting the grant of a patent has knowledge of any invention(s) related to the said invention, that has been known to the public through publication at the time of filing of the patent application. (Article 36(4)(ii) of the Patent Act)	o Relevant prior art must be assessed and bibliographic data given. Long lists of documents without any individual commentary are not helpful in identifying the most relevant prior art. Bare bibliographic data by themselves are generally not sufficient.	o In USPTO practice, prior art and/or background art may be found in the part of the disclosure entitled Background of the Invention as set forth in MPEP 608.01(c) (2) which states in part: 608.01(c) Background of the Invention

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			(2) Description of the related art including information disclosed under 37 CFR 1.97 and 1.98: A paragraph(s) describing to the extent practical the state of the prior art or other information disclosed known to the applicant, including references to specific prior art or other information where appropriate. o Where applicable, the problems involved in the prior art or other information disclosed which are solved by the applicant's invention should be indicated.
(iii) Problems which the invention aims to solve	o As “Problem to be Solved by the Invention”, an application should state at least one technical problem to be solved by a claimed invention. o However, the “Problem to be Solved by the Invention” is not required to be explicitly stated if a person skilled in the art can understand it without such an explicit statement, when looking into overall descriptions in the specification and drawings including statements of prior art or advantageous effects of the invention, taking	o The applicants are not obliged to explicitly state what problem the invention is intended to solve. They may do so or the problem may be deducible from the mere disclosure of the invention. In any case, wherever a patentable invention exists a problem can be formulated. A long list of various problems or "objects" (i.e. objectives) is neither required nor particularly helpful, especially when there is no indication which is to be considered as the main problem. The perceived problem may need to be changed	o where applicable, the problems involved in the prior art or other information which are solved by applicant's invention should be indicated in the Background of the Invention. o There is no requirement that applicant draft the specification in terms of problem-solution or that the applicant even be aware of the problems with the prior art. o An applicant is not permitted to make derogatory remarks concerning the inventions of others as set forth in MPEP 608.01(r) which states:

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	into consideration the common general knowledge as of the filing. (Note that a person skilled in the art could comprehend the technical problem when considering prior art which falls within the common general knowledge as of the filing.) o Further, in cases where an invention is deemed not based upon recognition of a problem to be solved like an invention developed based on an entirely new conception which is completely different from prior art or an invention which is based on a fortuitous discovery resulting from trials and errors (e.g., chemical substances), an application for such an invention is not required to state a problem to be solved. (Examination Guidelines Part I Chapter 1. Section 3.3.2 (1) ②)	during the examination procedure. Any problem finally stated must have had some basis in the application as filed (Article 123 (2)).	608.01(r) Derogatory Remarks About Prior Art Specification

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o "Statements of the detailed description of the invention which are to be in accordance with an ordinance of the Ministry of Economy, Trade and Industry under Article 36(4)(i) shall state the problem to be solved by the invention and its solution, or other matters necessary for a person having ordinary skill in the art to understand the technical significance of the invention." (Article 24-2 of the Regulations under the Patent Act)		The applicant may refer to the general state of the art and the advance thereover made by his or her invention, but he or she, is not permitted to make derogatory remarks concerning the inventions of others. Derogatory remarks are statements disparaging the products or processes of any particular person other than the applicant, or statements as to the merits or validity of applications or patents of another person. Mere comparison with the prior art are not considered to be disparaging per se.
(iv) Disclosure of the invention (means of solving the problems) - enablement requirement	o The detailed description of the invention shall be described in such a manner that a person skilled in the art to which the invention pertains can carry out the claimed invention. (Article 36(4)(i) of the Patent Act)	o Enablement is taken to mean the ability of the person skilled in the art to perform the invention on the basis of the information supplied in the description. o The basic consideration is, therefore, whether the information is sufficient or not for the addressee. In particular, the description must disclose any feature essential for carrying out the invention so that the skilled person can put the invention into practice without undue effort	o The separately stated requirements under 35 U.S.C. 112 of how "to make" and how "to use" the invention have become referred to in combination as the "enablement requirement". o While applicant is required to set forth the steps and/or apparatus for carrying out the invention in the disclosure, there is no requirement that the disclosure be presented in terms of "solving a problem". o The filing date is the reference point for

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		(Guidelines C-II, 4.9).	determining whether a disclosure is enabling. ... application sufficiency under Section 112, first paragraph, must be judged as of its filing date. It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file.
			The court in In re Glass answered in the negative the question: "If a disclosure is insufficient as of the time it is filed, can it be made sufficient, while the application is still pending, by later publications which add to the knowledge of the art so that the disclosure, supplemented by such publications, would suffice to enable the practice of the invention?" However, the court has approved the use of art coming into existence after the filing date of an application as evidence of the state of art existing on the filing date of an application.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			The court has not approved the use of a later publication disclosing a later existing state of the art in testing an earlier filed application for compliance with 35 U.S.C. 112, first paragraph.
(a) Amount of detail needed to satisfy the sufficiency of description requirement - functional vs. structural description	o In the case of "an invention of a product," various forms of expression such as function and others can be used as matters to define an invention in addition to the forms of expression such as combination of products or the structure of products. o On the other hand, for example, in the technical field where the structure of a product can hardly be predicted from its function, work, property or characteristics (hereinafter referred to "function or characteristics, etc."), it should be noted that the scope of an invention tends to be unclear in many cases as a result of defining the product by its function or characteristics, etc. (e.g. inventions of chemical substances). (Examination Guidelines Part I Chapter 1.	o In order that the description requirements are fully satisfied it is necessary that the invention is described not only in terms of its structure but also in terms of its function, unless the functions of the various parts are immediately apparent. o Indeed, in some technical fields (e.g. computers), a clear description of function may be much more appropriate than an over-detailed description of structure. Where an invention lies in realising what the problem is, the solution being obvious once the problem is stated, then the details given of the solution may be minimal. (Guidelines C-IV, 11.6 and C-II, 4.5 to 4.6).	o The applicant describes the invention in the specification in terms of both functional and structural statements. The USPTO does not prefer one form of statement over the other as long as the invention is sufficiently described. 35 U.S.C. 112 contains no requirement for structural disclosure.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	Section 2.2.2 (4) ①②		
(b) Definition of "person skilled in the art"	o The term "a person having ordinary skill in the art to which the invention pertains" in Article 36 (4)(i) is considered to mean a person who has ability to use ordinary technical means for research and development (including comprehension of document, experimentation, analysis and manufacture) and to exercise ordinary creativity in the art to which the invention pertains. (Examination Guidelines Part I Chapter 1. Section 3.2 (1))	o The Guidelines C-IV, 11.3 define the skilled parson as follows; o The person skilled in the art should be presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem.	o While there is no absolute definition of "person of ordinary skill in the art", U.S. case law has stated that such a person would possess ordinary or fair information for a particular technology. This person would not be one having more than ordinary skill or a genius in the art or more than one person such as a team of persons having ordinary skill in the art. The knowledge and skill of such a person would vary from case to case depending upon the technology. Therefore, an enabling disclosure would not have to contain every detail for the invention but must be sufficient to enable one of ordinary level in that particular technology to have the understanding to make and use the invention.
		The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability. There may be instances where it is	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		more appropriate to think in terms of a group of persons, e.g. a research or production team, than a single person. This may apply e.g. in certain advanced technologies such as computers or telephone systems and in highly specialised processes such as the commercial production of integrated circuits or of complex chemical substances. o This definition in the Guidelines comes under the heading of inventive step.	
- whether the same as for inventive step	o The term "a person having ordinary skill in the art to which the invention pertains" in Article 29 (2) is considered to mean a person: who has the common general knowledge in the art to which the claimed invention pertains at the time of filing an application, and has ability to use ordinary technical means for research and development; who has ability to exercise ordinary creativity in selecting materials and changing designs; and who is able to comprehend as his/her own knowledge	o There is no distinction made between the skilled person assessing inventive step and the skilled person assessing sufficiency of the description. o For assessing inventive step or non-obviousness, the person skilled in the art is expected to have access to all the relevant documents in the state of the art. However, in determining sufficiency of the description this same person should not be expected to undertake any search to obtain necessary information missing from the description	o 35 U.S.C. 103 refers to "a person having ordinary skill in the art" while 35 U.S.C. 112 refers to "any person skilled in the art". Although similar language is employed in the two sections, in USPTO practice there is a difference in the level of skill attributable to a person in the art depending on whether the attribution is occurring under Section 103 or Section 112. o This difference in attribution of skill level results from the art that is available to skilled persons under each section.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	all technical matters in the state of the art in the field to which a claimed invention pertains at the time of filing a patent application. In addition, a person skilled in the art is supposed to be able to comprehend as his/her own knowledge all technical matters in the field of technology relevant to a problem to be solved by an invention. Further, there may be cases where it is more appropriate to think in terms of "a group of persons" than a single person. (Examination Guidelines Part I Chapter 2. Section 2.2. (2))	itself. Nevertheless, common general knowledge may be relied on to fill a gap in the description.	o Prior art that will negate novelty under Section 102 or evidence a lack of inventive step under Section 103 will not necessarily enable a person skilled in the art to practice the invention. For example, art that teaches how to make the invention which may bar an application under Section 102 may not teach how to use the invention and therefore not be sufficiently enabling to support an application. Additionally, prior art that is available under Section 102(e)/103 is not necessarily available to prove enablement.
- relevant art		o Relevant art can be broadly thought of as that which would cause the skilled reader to react to the situation faced by the applicants. The closest prior art can usefully be thought of as that providing the same or similar effects and having the most features in common with the invention. Sometimes, when the inventive step in a claim can be attacked from different standpoints, the	o For enablement purposes, the relevant art is not only the art where the problem has arisen or where the solution to the problem is found, which may be independent of the specific industry, but also the art which would afford the "best chance" of enablement. o Relevant art for enablement, must be readily available and known to one of ordinary skill in the art prior to the filing date

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		closest prior art can only be properly identified after one or more stages in the examination process.	of the application.
- use of prior art in determining enablement	o The detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing. (Examination Guidelines Part I Chapter 1. Section 3.2 (1)) o The common general knowledge means technologies generally known to a person skilled in the art or matters clear from empirical rules. Therefore, the common general knowledge includes method of experimentation, of analysis, of manufacture, etc., as far as they are generally known to a	o Enablement is taken to mean the ability of the person skilled in the art to perform the invention on the basis of the information supplied in the description. This person is not expected to undertake any search to obtain necessary information missing from the description itself. However, common general knowledge may be relied on to fill a gap in the description. As "common general knowledge" can generally be considered the information contained in basic handbooks, monographs and textbooks on the subject in question o As an exception, it can also be the information contained in patent specifications or scientific publications, if the	o The prior art used in determining enablement must be readily available and known to one skilled in the art as of the date of filing of the application. o Relevant prior art (or inventive step purposes would include subject matter invented by another in the U.S. who has not abandoned, suppressed or concealed it (35 U.S.C. 102(g)/103) whereas that relevant prior art would not be useful for enablement purposes if the invention was not publicly available.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	person skilled in the art. Whether or not a certain technical matter is generally known to a person skilled in the art should be determined based upon not only how many documents show the technical matter but also how much attention has been given to the technical matter by such a person. (Examination Guidelines Part I Chapter 1. Section 2.2.2 (3))	invention lies in a field of research which is so new that the relevant technical knowledge is not yet available from textbooks.	
(c) Incorporation by reference	o The detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing. (Examination Guidelines Part 1 Chapter 1. 3.2 (1)) Therefore, if "a Person Skilled in the Art" who is supposed to have ordinary skill cannot understand how to carry out the invention on the basis of teachings in the specification and	o The general requirement for a European application is that is should be self-contained. o Consequently although any prior art document may be referred to, incorporation of the whole or part of its content by a mere reference thereto and/or by merely stating that its content is incorporated is not allowed where the reference relates directly to the disclosure of the invention.	o An application must be complete in and of itself at the time of filing in order to comply with the disclosure requirements of 35 U.S.C. 112. However, USPTO practice does permit an applicant to incorporate material into the specification by reference to patents, patent applications and publications. The criteria for incorporation of material set forth in 37 CFR 1.57(b) and MPEP 608.01(p) depends upon whether the material is considered "essential" or "nonessential".

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	drawings taking into consideration the common general knowledge as of the filing, then, such a description of the invention should be deemed insufficient for enabling such a person to carry out the invention. (Examination Guidelines Part I Chapter 1. Section 3.2 (2))		
		o Under these circumstances, when the document referred to was publicly available before the filing date of the application, at least a summary of the document should be incorporated explicitly in the description. If the document referred to was not publicly available before the filing date, then amendment of the description on the basis of this document is only possible if, firstly, a copy of the document was furnished to the EPO on or before the filing date and, secondly, the document was made available to the public no later than the publication date of the application (Guideline C-II, 4.19).	o "An application for a patent when filed may incorporate 'essential material' by reference to (1) a United States patent or (2) a U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. 'Essential material' is defined as that which is necessary to (1) provide a written description of the claimed invention, and of the manner or process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by 35 U.S.C. 112, 1st paragraph, or (2) describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by 35 U.S.C. 112, 2nd
			paragraph, or (3) describe the structure, material or acts that correspond to a claimed means or step for performing a specified function as required by 35 U.S.C. 112, 6th paragraph. See 37 CFR 1.57(c) and MPEP 608.01(p).
			o Nonessential material may be incorporated by reference to U.S. patents, U.S. patent application publications, foreign patents, foreign published applications, prior and concurrently filed commonly owned U.S. applications, or non-patent publications. An incorporation by reference by hyperlink or other form of browser executable code is not permitted. See 37 CFR 1.57(d). o Although the filing date of an application is

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			the appropriate reference point in determining whether the application was submitted with an enabling disclosure an original incorporation by reference of essential material may be canceled and the actual material referenced by the incorporation inserted into the pending application, for example, if applicant comes to believe that the incorporated material is not available to the public.
			o The amendment adding the previously incorporated material must be accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. See 37 CFR 1.57(f).
			o 37 CFR 1.57(a) provides that, if all or a portion of the specification or drawing(s) is inadvertently omitted from an application, but the application contains a claim under 37 CFR 1.55 for priority of a prior-filed foreign application, or a claim under 37 CFR 1.78 for

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			the benefit of a prior-filed provisional, nonprovisional, or international application, that was present on the filing date of the application, and the inadvertently omitted portion of the specification or drawing(s) is completely contained in the prior-filed application, the claim for priority or benefit shall be considered an incorporation by reference of the prior-filed application as to the inadvertently omitted portion of the specification or drawings. See MPEP 201.17.
(d) Risk of future "unenablement"	o When trademarks are used for what can be indicated otherwise, there are some cases where the requirements under Patent Act Article 36(4) or (6) are not met. (Examination Guidelines Part 1 Chapter 1 Section 4. (4))	o Risk of future "unenablement" is taken to relate to the circumstance where a named product or item, critical to the performance of the invention, is not ascertainable (e.g. because it has long ceased to be manufactured). o The EPO practice is to call for a definition of the product/item at the outset so that the invention is "enabled" without reliance on the name. The exceptions here are internationally accepted terms like "Venturi" tubes and "Bowden" cables. Registered	o 1) Where a claimed process or apparatus relies on the use of a particular chemical composition identified by a trademark wherein the composition is clearly described in the specification or is known to those skilled in the art at the time the application was filed and was readily available as an article of commerce at that time. The owner/manufacturer of the trademarked composition may later change or discontinue making the composition and the worker skilled in the art may not then be able to

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		Trade Marks should be acknowledged as such. o Micro-organism deposits are intended to prevent "unenablement" for the maximum lifetime of the patent.	duplicate or prepare a substitute, thus rendering the process or apparatus unenabling. o 2) A chemical process or product produced therefrom which relies upon a unique strain of microorganism:
	(Refer to 7(8) Trademark)		a) If the microorganism is not made freely available by deposit in a permanent culture collection or the organism is unstable, those skilled in the art may again not be able to practice the invention and b) Although the microoganism culture critical to the practice of the invention is deposited in a permanent culture collection the culture undergoes a physical change that renders it unusable o The court in In re Coleman, recognized that were a specification recites a trademark or trade name there is some possibility that the specific materials disclosed may be removed from the market or that the trademark or trade name may be applied to a significantly different product.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			o However, where the risk is small and the occurrence of the event of nonenablement is too remote and speculative, a rejection under the first paragraph of 35 U.S.C. 112 cannot be supported.
			o The specification must guide those skilled in the art to its successful application. The minutiae of descriptions or procedures perfectly obvious to one of ordinary skill in the art yet unfamiliar to laymen need not be set forth. The test of sufficiency of disclosure to practice the invention is not merely quantitative as a considerable amount of experimentation is permissible if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. - unreasonable experimentation o While some experimentation is acceptable in order to practice the invention the degree of

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			experimentation required must not be undue, unreasonable, extended and require ingenuity beyond that to be expected of one of ordinary skill in the art.
(e) Disclosure requiring experimentation - reasonable experimentation - unreasonable experimentation	o The detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing. (Examination Guidelines Part 1 Chapter 1 Section 3.2 (1)) Therefore, if "a Person Skilled in the Art" who is supposed to have ordinary skill cannot understand how to carry out the invention on the basis of teachings in the specification and drawings taking into consideration the common general knowledge as of the filing, then, such a description of the invention should be deemed insufficient for enabling such a person to carry out the invention. For example,	o No undue effort is to be expected from the skilled person either by way of search or experimentation. However, experimentation that leads to a quick and reliable way of obtaining the desired result is a reasonable expectation where the manner and outcome of such experimentation is described. Similarly, routine methods of experimentation or analysis extending the particular teaching of the description to cover the whole field claimed can be expected of the skilled reader (Guidelines C-III, 6.3). o By contrast, where there are well-founded reasons to believe that a skilled person would not be able to extend the teaching of the description to the whole of the field claimed by using routine methods of	o While sufficient information must be given in the specification so that one skilled in the art can practice the invention it is not fatal if some experimentation is required in order for one skilled in the art to actually practice the invention so long as undue or unreasonable experimentation is not required. The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness and will depend on the facts of each case. The following factors may be considered in determining whether the experimentation required was undue or unreasonable (In re Wands): 1) the quantity of experimentation needed to make or use the invention based on the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	if a large amount of trials and errors or complicated experimentation are needed to find a way to carry out the invention beyond the reasonable extent that can be expected from a person skilled in the art, such a description should not be deemed sufficient. (Examination Guidelines Part I Chapter 1. Section 3.2 (2))	experimentation or analysis, then the applicants are called on to furnish convincing evidence to the contrary or to restrict their claims accordingly. Such reasons should preferably be supported by a document.	content of the disclosure; 2) the amount of direction provided by the inventor; 3) the existence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the level of one of ordinary skill;
		o Where the successful performance of an invention depends on chance, the description is held to be insufficient. That is, in following the instructions for carrying out the invention, the skilled reader finds either that the alleged results are unrepeatable or only obtainable in a totally unreliable way. o The description of alleged inventions working contrary to established physical laws is also held to be insufficient, at least if the claims are directed to the functioning of such an apparatus (Guidelines C-II, 4.11).	7) the level of predictability in the art; and 8) the breadth of the claims. - reasonable experimentation o A disclosure complies with 35 U.S.C. 112 even though some experimentation is required, provided the experimentation is not an undue amount or unreasonable.

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(f) How to make - availabilty of starting materials	o For an invention of a product, the description shall be stated so as to enable a person skilled in the art to make the product. For that purpose, the manufacturing method must be concretely described, except the case where a person skilled in the art can manufacture the product based on the description in the specification and the drawings, and the common general knowledge as of the filing. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (2) ②) o For an invention of a process for manufacturing a product, various types exist including a process for producing goods, a process for assembling a product, a method for processing a material, etc. Any of these consists of such three factors as i) materials, ii) process steps and iii) final products. For an invention of a process for manufacturing a product, the description shall be stated so as to enable a person skilled in the art to manufacture the product by using the process.	o Information that can only be derived from a thorough search is not common general knowledge. That is, the mere identification of starting or intermediate materials used in the production of, say, a chemical compound is not necessarily sufficient if the skilled reader is unable to find out from a document referred to in the description or from common general knowledge how to obtain these materials.	o An invention must be adequately disclosed in the specification so as to permit one skilled in the art to make and use the claimed invention. o Apparatus, methods or materials essential to make the inventive product or carry out the inventive process even though not recited in the claim must be adequately disclosed. The issue in In re Ghiron was directed to applicant's failure to disclose suitable data processing apparatus for carrying out the method claims.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	Thus, these three factors shall in principle be described in such a manner that a person skilled in the art can manufacture the product when taking into account the overall descriptions of the specification, drawings and the common general knowledge as of the filing. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (4) ②)		
			o With respect to cases involving processes or products which require the use of a particular strain of microorganisms, the court in In re Argoudelis, held that deposit of a culture of the strain in the permanent culture collection of the U.S. Department of Agriculture depository was sufficient to make the strain publicly available and to comply with 35 U.S.C. 112. Under USPTO practice, a microorganism which provides an essential starting material or acts to transform an initial material into the desired product must be placed in a permanent culture collection and be made available to the public once a

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			patent issues in order to comply with the how to make aspect of the enablement requirement.
(g) How to use - utility and operability	o For an invention of a product, the description shall be stated in the detailed description of the invention so as to enable a person skilled in the art to use the product. To meet this, the way of using the product shall be concretely described except where the product could be used by a person skilled in the art without such explicit description when taking into account the overall descriptions of the specification, drawings and the common general knowledge as of the filing. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (2) ③) o In the case of inventions in technical fields where it is generally difficult to infer how to	o The description should indicate explicitly the way in which the invention is capable of industrial exploitation, when this is not self-evident. Reference is also mode to (3) (iv) (a) and (e) above.	o The how to make and use requirement under 35 U.S.C. 112, first paragraph parallels a similar requirement under 35 U.S.C. 101 which sets forth that in order to be patentable the invention must be useful. o A rejection under Section 101 for lack of utility will necessarily entail a rejection under Section 112, first paragraph in that if the invention lacks utility the specification cannot have taught how to use the invention. However, the converse is not necessarily true in that a specification that fails to adequately disclose how the invention may be practiced may in fact disclose a utility for the invention.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	make and use a product on the basis of its structure (e.g., chemical substances), normally one or more representative embodiments or working examples are necessary which enable a person skilled in the art to carry out the invention. Also, in the case of use inventions (e.g., medicine) using the character of a product etc., the working examples supporting the use are usually required. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (5))		
(h) Proof of enablement	o Where an examiner makes a notice of reason for refusal on the ground of violation of enablement requirement under Article 36(4)(i), (s)he shall identify the claim which violates the requirement, make clear that the ground of refusal is not a violation of Ministerial Ordinance requirement but a violation of enablement requirement under Article 36(4)(i), and point out particular descriptions, if any, which mainly constitute the violation. When sending a notice of reason for refusal, the examiner should specifically point out a	o See (3) (iv) (e) above.	o In U.S. practice it is the USPTO that has the "burden of giving reasons, supported by the record as a whole, why the specification is not enabling". "The first paragraph of Section 112 requires nothing more than objective enablement" wherein a specification's disclosure that contains statements which on their face appear to establish enablement the statements "must be taken as in compliance ... unless there is reason to doubt the objective truth of the statements...". It is not required that "a

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	concrete reason why the application violates the enablement requirement. The reason above should be supported by reference documents. Such documents are, in principle, limited to those that are known to a person skilled in the art as of the filing. However, specifications of later applications, certificates of experimental result, written oppositions to the grant of a patent, and written arguments submitted by the applicant for another application etc. can be referred to for the purpose of pointing out that the violation stems from the descriptions in the specification and drawings being inconsistent with a fact generally accepted as scientifically or technically correct by a person skilled in the art. (Examination Guidelines Part I Chapter 1. Section 3.2.3 (1)) o Against the notice of reason for refusal, an applicant may argue or clarify by putting forth written arguments or experimental results, etc (Note). Where the applicant's argument is		specification convince persons skilled in the art that the assertions therein are correct ...".

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	confirmed to be adequate by examining the submitted evidence, the reason for refusal shall be deemed to overcome. Where the applicant's argument does not change the examiner's conviction at all or where it succeeds in denying the examiner's conviction only to the extent that truth or falsity becomes unclear, the examiner makes a decision of refusal on the ground of the notice of reasons for refusal which is earlier notified. (Note) For example, through a written opinion or a certified experiment result, etc., the applicant may clarify that the experiment or the method of analysis not considered by the examiner is actually pertaining to the common general knowledge as of the filing, and that a person skilled in the art can carry out the claimed invention based on such an experiment or method for analysis as well as the description in the specification and the drawings. (Examination Guidelines Part I Chapter 1.		

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	Section 3.2.3 (2))		
			o Should the U.S. examiner be able to provide reasons for questioning the objective truth of the statements relied on in the disclosure to establish enablement, the applicant may subsequently provide affidavit evidence not for the purpose of correcting any deficiency in the original disclosure but to prove that the disclosure originally proved was in fact enabling.
(v) Action or working of the invention	o It is required to describe how each matter defining the invention of the product works (role of each matter) (namely, "operation" of each matter) if a person skilled in the art needs it for using the product of an invention. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (2) ③)	o It is expected that the description teaches not only what the invention is but also how it works (see (3) (iv) (a) and (e) above). However, a statement of the theory or principle behind any effect or working is not required.	o While the specification must be specific enough to enable one skilled in the art to practice the invention, it is not required that the theory or scientific principle underlying the invention be explained.
(vi) Working examples (Best mode of practicing the invention)	o when embodiments or working examples are necessary in order to explain the invention in such a way that a person skilled in the art can carry out the invention, "the mode for carrying	o At least one specific way of performing the invention must be described (Rule 42(1)(e)).	o In USPTO practice there is not necessarily a relationship between the presence of a working example in the specification and the requirement to disclose the best mode. A

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	out the invention" should be described in terms of embodiments or working examples. In cases where it is possible to explain the invention so as to enable a person skilled in the art to carry out the invention, neither embodiments nor working examples are necessary. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (5))		working example may or may not represent the best mode, particularly as the best mode need not be supplied by use of a working example (see section 2. (3) (vi) (a)).
			o Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. o Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. o Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			described using the past tense (MPEP 608.01(p)).
(a) What is a mode	o At least one mode that an applicant considers to be the best among the “modes for carrying out the invention” showing how to carry out the claimed invention in compliance with the requirements in Article 36(4)(i) should be described in the detailed description of the invention. (Note) The “mode for carrying out the invention” referred to in this Guideline is the same as prescribed in the Regulation 5.1-(a)(v) under PCT (Patent Cooperation Treaty). (Examination Guidelines Part I Chapter 1. Section 3.2.1 (1))	o A "mode" is taken to mean "manner" or "way". o To be valid, the mode or way of carrying out the invention as described must lie within the scope of the broadest claim.	o 35 U.S.C. 112, first paragraph requires that the specification "shall set forth the best mode ... of carrying out" the invention (see also 37 CFR 1.71). o The requirement for disclosure of a best mode is a question separate and distinct from the question of how to make and use the invention. o "Nonenablement is the failure to disclose any mode". Therefore, "if an invention pertains to an art where the results are predictable, e.g. mechanical as opposed to chemical art, a broad claim can be enabled by disclosure of [any] single embodiment". o However, should an alternative embodiment

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			than that disclosed be known to be superior the failure to disclose that alternative would result in a fatally defective disclosure under the best mode requirement of Section 112 notwithstanding applicant's compliance with the enablement requirement.
	o It is proper to describe the mode that an applicant considers to be the best about the modes for carrying out the invention in terms of the requirements in Article 36(4)(i). However, even if it is clear not to describe the mode that an applicant considers to be the best, it does not constitute a reason for refusal.		o While the enablement requirement may be satisfied by consideration of the level of skill in the art, the best mode requirement requires explicit disclosure of that which the inventor contemplates as the preferred embodiment. o The presence of a working example is not necessary in order that the specification teach how to make and use the invention (see Section 2. (3) (iv) (e), supra) or to comply with the best mode requirement. o The applicant "may represent his ... best mode just as well by a preferred range of conditions or group of reactants" or otherwise

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			as well "as by a working example which employs unitary values of each variable involved".
(b) Best mode contemplated by inventor	See (3)(vi)(a) above.	o There is no requirement in the EPC to describe the best way of performing the invention. o However, it is in the applicant's best interest that information in the application as to how to carry out the invention be a sound basis for the advantageous effect alleged, in support of inventive step.	o 35 U.S.C. 112 requires only that the best mode "contemplated" by the inventor be disclosed. The purpose of this requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived. o How an inventor should disclose the best mode is left to the inventor. While the best mode must be disclosed it need not be so labeled.
			o Whether the best mode has been adequately disclosed is subject to review and is a question of fact. However, as there is "no objective standard by which to judge the adequacy of a best mode disclosure ... only evidence of concealment (accidental or intentional) will be considered. That evidence, in order to result in affirmance of a best mode rejection, must

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment". Such possibility exists even though there may be "a general reference to the best mode". o Improvements in the invention made by another that represent the best mode for carrying out the invention must be disclosed by the inventor if known to him at the time of filing the application.
(c) Critical date with regard to disclosing best mode - continuing applications (i.e. Must applicant disclose a better mode discovered in the interim?)	o No comment	o No comment	o The critical date with regard to disclosing a best mode is the best mode contemplated as of the date of filing of the application. Hence, subsequent discovery of a best mode need not be disclosed in an application previously filed. o Whether the inventor must disclose a best mode discovered subsequent to the filing of the parent application in a continuation or continuation-in-part application is still not settled in U.S. case law.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			o For a U.S. application to be accorded the benefit of the filing date of a foreign application under 35 U.S.C. 119(a), the foreign application must satisfy the requirements of Section 112, first paragraph. (Utility and how to use requirements under Section 112, first paragraph were in issue.) The foreign priority application must also comply with the best mode requirement under Section 112, first paragraph in order for the U.S. application to be accorded the priority date of the foreign application. o Additionally, the U.S. application must disclose any best mode discovered subsequent to the filing of the foreign priority application.
(vii) Advantageous effects or merits of the invention	o It is not required under the Ministerial Ordinance requirement to state an advantageous effect of a claimed invention over the relevant prior art. However, it is an applicant's advantage to describe an advantageous effect of a claimed invention over the relevant prior art because such advantageous effect, if any, is taken into	o Any advantageous effects of the invention with respect to the background art should be stated (Rule 42(1)(c)). o However, statements of advantage introduced as a result of acknowledgement of art found in the search must not introduce new matter (Guidelines C-II, 4.5). o Disparaging statements with respect to the	o The specification explains the invention by customarily comparing the invention with the prior art, and in so doing, gives the improvements over the prior art. o However, U.S. law does not require applicant to explain the invention in terms of (1) "problem-solution" or (2) the "advantageous effects" or "merits of the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	consideration as a fact to support to affirmatively infer the existence of inventive step (Refer to Examination Guidelines Part II, Chapter 2.(Novelty and Inventive Step) Section 2.5(3)). Also, descriptions of advantageous effects could teach the problem to be solved and could substitute the descriptions of the problem to be solved. Therefore, an applicant should describe an advantageous effect of a claimed invention over the relevant prior art, if any, as far as (s)he knows. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (1))	background art are not allowed.	invention".
			o If the invention has been explained in terms of its advantages over the prior art or its merits, this explanation appearing in the specification, will not be considered in the claim unless such a statement appears therein. That is, if the claim only sets forth the elements of the invention the examiner will not read into the claimed invention the additional limitation of the advantageous

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			effects or the merits of the invention.
			o The phrases "advantegeous effects" or "merits of the invention" are not a phrase of art for U.S. practice.
(viii) Industrial applicability	o The main paragraph of Article 29 (1) of the Patent Act provides that any person who has made an industrially applicable invention may obtain a patent.	o The description shall: indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry. (Rule 42(1)(f)). However, the industrial application of a sequence or a partial sequence of a gene must always be disclosed in the patent application (Rule 29(3)).	o 35 U.S.C. 101 requires that the invention sought to be patented be "useful", which requirement is referred to as the utility requirement. o To comply with the utility requirement an invention need not be superior to that which is already known.
	o Industrial applicability is indicated only when it is not clear from the description of the nature of invention, specification, etc.. Industrial applicability is clear from the description of the nature of invention, specification, etc. in many cases, and needs not to be described explicitly in these cases. (Examination Guidelines Part I Chapter 1. Section 3.3.2 (4))	Art 52(1) has been brought into line with Art 27(1) TRIPs, with a view to make it plain that European patent protection is available to technical inventions of all kinds.	o Utility questions in USPTO practice arise when a claimed invention does not have a well-established utility and applicant fails to assert a specific, substantial, and credible utility for the claimed invention in the specification. The credibility prong of the utility requirement is at issue when, for example, an asserted utility would violate a scientific principle or a claimed invention

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			would be inoperative (e.g., a perpetual motion device). More frequently, utility issues arise in the context of the requirement for a specific and substantial credible utility in applications disclosing chemical and biological materials (MPEP 2107.01). A "specific" utility is a utility that is specific to the subject matter claimed and can provide a well-defined and particular benefit to the public. This contrasts with a general utility that would be applicable to the broad class of the invention.
		Consequently, exclusions relating to "methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human and animal body" have been transferred to Art 53 (Exceptions to patentability), at paragraph (c). The same paragraph stipulates that the exclusion shall not apply to products, in particular substances or compositions, for use in any of these methods.	For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Regarding the "substantial" utility prong, an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. An asserted use must show that the claimed invention has a significant and presently available public benefit.
(4) Brief description of the drawings	o In the "Brief Explanation of the Drawings ", there should be given a description reading, for example, "Fig. 1 is a plane view, Fig. 2 is an elevation view, and Fig. 3 is a sectional view", and an explanation of the reference numerals or signs representing the essential parts of the drawings. (Form 29)	o A brief description of the drawings is required and is generally inserted before any detailed description of the invention.	o When drawings are filed with an application, a reference to and brief description of the drawings as set forth in 37 CFR 1.74 must be included, preferably following the brief summary of the invention. 37 CPR 1.74 states o When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals (preferably the latter).

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
3. Claims			
(1) General	o The scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which an applicant requests the grant of a patent. In such case, an invention specified by a statement in one claim may be the same invention specified by a statement in another claim. (Article 36 (5) of the Patent Act) o The statement of the claim shall comply with each of the following items: (i) the invention for which a patent is sought is stated in the detailed description of the invention; (ii) the invention for which a patent is sought is clear; (iii) the statement for each claim is concise; and (iv) the statement is composed in accordance with the relevant Ordinance of the Ministry of Economy, Trade and Industry. (Article 36 (6) of the Patent Act)	o The European patent application must contain one or more claims (Article 78 (1) (c)). Under Rule 40(1), it is not necessary that an applicant provide any claims in order to obtain a date of filing. If the application is filed without claims, but satisfies all requirements for obtaining a date of filing, the applicant will be requested to provide at least one claim later (Rules 57(c) and 58). o The applicant has the option of incorporating by reference the claims of a single earlier application. However, the indication that he wishes the claims of the earlier application to take place of the claims in the application as filed must be made on the date of filing (Rule 40 (2) and (3) and Rule 57(c)). See also Guidelines A-II, 4.1.3.1 and A-III, 15). o According to Article 84 the claims define the matter for which protection is sought. They must be cleat and concise, and be	o As one of the items for a complete nonprovisional application, the USPTO requires every nonprovisional application when filed, to contain at least one claim, so that the application can be accorded a filing date (37 CPR 1.53). The claim must particularly point out and clearly define the subject matter of the invention. (35. U.S.C. 112). o There are two purposes for a claim - patentability and infringement determinations. A claim is used to define what applicant regards as the invention and distinguish the invention from the prior art. The examiner makes a patentability (statutory subject matter, clarity, disclosure requirements, loss of rights, novelty, and Inventive step) determination of the claim. Once a patent is granted, the claim is used to determine the extent of the coverage, the metes and bounds of the invention, for infringement purposes.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application. (Article 70 (1) of the Patent Act)o In the case of the preceding paragraph, the meaning of each term used in the scope of claims shall be interpreted in consideration of the statements in the description and drawings attached to the application. (Article 70 (2) of the Patent Act)	supported by the description. o The description and drawings are used to interpret the claims (Article 69 (1)).	
(2)Claiming format			
(a) Number of claims	o Claims are not limited in number, provided that requirements for unity of invention are met.	o The applicant may file as many claims as he thinks are necessary in order to cover the whole scope of his invention. The number should be reasonable according to Rule 43(5). The requirement in Article 84 that claims have to be concise provides the office with a means to object to an unreasonable number and/or repetitious claims. o Several independent claims in the same category are allowable according to Rule 43(2) but only "where it is not appropriate,	o In order to properly define the invention from various perspectives, applicant may submit any reasonable number of claims based on the nature and scope of the invention and the state of the prior art. o Applicant may submit any reasonable number of independent claims within or among the statutory categories (i.e. process, machine, manufacture or composition of matter). o Effective November 1, 2007, the rules of

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		having regard to the subject-matter of the application, to cover this subject-matter by a single claim".	practice for the examination of claims in an application (37 CFR 1.75) has been revised to provide that if the number of independent claims is greater than 5 or the number of total claims is greater than 25, the Office will require the applicant to submit an examination support document (ESD) complying with 37 CFR 1.265 covering all of the claims in the application. If applicant chooses not to file an ESD, the application must be amended to contain no more than 5 independent claims and no more than 25 total claims. [Note: In view of the preliminary injunction issued by the U.S. District Court for the Eastern District of VA on Oct. 31, 2007, the changes to the rules of practice in the claims and continuation final rules did not go into effect on Nov. 1, 2007.]

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(b) Structure of claims (e.g. Markush claims, Jepson type claims)	o Markush type claims are an accepted. Also, it is not restricted in the interpretation of the scope of patented invention. o The statement for each claim shall be concise. (Article 36 (6)(iii) of the Patent Act) o There are some cases where it is violating the requirement of Article 36(6)(iii)if a claim is expressed in alternatives (e.g., a Markush type claim for chemical compounds) and the number of alternatives is so large that the conciseness is extremely damaged. Consideration should be taken into the followings, in determining whether the conciseness is extremely damaged. ① In a case where a significant structural element is not shared by the alternatives, less number of alternatives should be deemed so large that the conciseness is extremely damaged than in a case where a significant structural element is shared by the alternatives. ② In a case where the alternatives are	oThe structure of claims is specified in Rule 43 (1) which requires that "... whenever appropriate claims shall contain (a) a statement indicating the designation of the subject-matter of the invention and those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, are part of the prior art; (b) a characterising portion, beginning with the expression "characterised in that" or "characterised by" and specifying the technical features for which, in combination with the features stated under sub-paragraph (a), protection is sought.	o There are three portions to the structure of a claim: the preamble, the transitional phrase and the body. The preamble introduces the invention and may set forth the environment or intended use. The body recites the invention limitations in terms of process steps for a method claim or elements for a product or an apparatus claim. The transitional phrase not only connects the preamble with the body, but indicates to others whether the recited limitations in the body are only part of the elements or steps that make up the invention defined in the specification or are all of the elements or steps. o Jepson and Markush claims follow the same structural format of having a preamble, transitional phrase and body.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	expressed in a complicated way, such as the conditional options, less number of alternatives should be deemed so large that the conciseness is extremely damaged than otherwise. (Examination Guidelines Part I Chapter 1. Section 2.2.3.1 (2))		
		This format called "two-part form of claims" in fact only applies to independent claims. Claims in the two-parts form are appropriate if there exists a clearly defined prior-art from which the subject-matter claimed differs by further technical features. o The so-called Markush type claim is an accepted format of claims for the EPO and is mainly used in the field of chemistry. However, Markush type claims may give rise to unity objections if they do not cover alternatives of a similar nature (Guidelines, C-III, 3.7 and 7.4.1).	o The Jepson claim begins with a preamble that states the limitations of the old device or process; a transitional phrase noting the improvement in the device or process, such as, the improvement comprising; and, the body of the claim which states the new features. o A Markush claim is generally used in the chemical practice to present alternative limitations in the body of the claim. A Markush claim is used where there is no commonly recognized generic expression which is commensurate in scope to cover all of the alternatives.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o Although Jepson type claims have a two part structure, they may lack clarity. "In an X ... the improvement Y..." is ambiguous as to whether X. X+Y or only Y is being claimed. The obscurity is compounded if the first part is of apparatus features and the second part relates to a method.	
(c) Categories	o Categories of inventions are divided into two main categories i.e. an invention of a product and an invention of a process. A category of an invention of a process includes an invention of a process for manufacturing products. (Article 2 (3) of the Patent Act) o Such terms in a claim as *"system"* (e.g., *"telephone system"*) are interpreted as those meaning the category of a product. *"Use"* is interpreted as terms meaning a method for using things which is categorized into a "process." "Use of substance X as an insecticide" is interpreted as terms meaning "method for using substance as an insecticide." "Use of substance X for the manufacture of a	o The Guidelines (C-III, 3.1) define two basic categories of claims: - claims for physical entities: products, apparatus: - claims for activities: process, use.	o The four different categories (i.e. statutory classes in U.S. law) of inventions are set forth in 35 U.S.C. 101. They are process, machine, manufacture and composition of matter.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	medicament for therapeutic application Y" is interpreted 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))		
	o If the category of an invention for which a patent is sought is unclear, or something that falls in neither products nor processes is stated in a claim, the claimed invention becomes unclear. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (3))	o The EPC however gives a different meaning to the word "categories" for the purpose of Rule 44 (Unity of invention) which defines the categories of the invention which may be included in a single patent application. The categories are: products, process, apparatus or use. The same definition is found in Rule 43(2). However, these Rules are not considered as really being intended to define what is to be understood by the word "categories". o There is no limitation in the number of categories in one set of claims. The number of categories used by the applicant is only checked vis-a-vis the requirement of clarity and conciseness and the Guidelines (C-III,	o A process is a manipulation according to an algorithm or technique. It is generally regarded as "doing something to or with something according to a schema". o A machine includes any apparatus of a mechanical nature. o A manufacture includes any article devised by man that does not fall within the categories of compositions of matter or machines. o A composition of matter includes any intermixture of two or more existing ingredients. New molecules and chemical compounds fall within this category.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		3.2) recognize the need for claims in more than one category in order to properly cover the whole scope of subject-matter disclosed in the application. Examiners are instructed "not (to) adopt an over-academic or rigid approach to the presence of a number of claims which are differently worded but apparently of similar effect".	
		o Rule 43(2) even allows different independent claims belonging to the same category where it is not appropriate to cover the subject-matter in a single independent claim.	
(d) Independent and dependent claims	o Claims are classified into independent form claims and dependent form claims. Independent form claims are those defined without referring to other claims, while dependent form claims are those which refer to other preceding claims. The two types of claims differ only in the form of description, and are treated in the same manner. (Examination Guidelines Part I Chapter 1. Section 2.2.4)	o An independent claim is a claim which stands on its own, without referring to any other claim. It should contain all the essential features of the invention. Rule 43(3) makes it clear that such a claim may be followed by one or more claims concerning particular embodiments of the invention. The expression "dependent claim" appears in Rule 43(4) which defines it as "any claim which includes all the features of any other	o Applicant is permitted to claim an invention by presenting one or more claims in independent and dependent form. o Applicant may submit any reasonable number of independent claims within or among the statutory categories. This allows applicant sufficient latitude to adequately claim the invention. o Effective November 1, 2007, the rules of practice for the examination of claims in an

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		claim". o To be considered as dependent a claim should be in the same category as the claim to which it refers back so that there are claims which refer to a previous claim and are not dependent (Guidelines C-III, 3.4).	application (37 CFR 1.75) has been revised to provide that if the number of independent claims is greater than 5 or the number of total claims is greater than 25, the Office will require the applicant to submit an examination support document (ESD) complying with 37 CFR 1.265 covering all of the claims in the application. If applicant chooses not to file an ESD, the application must be amended to contain no more than 5 independent claims and no more than 25 total claims. [Note: In view of the preliminary injunction issued by the U.S. District Court for the Eastern District of VA on Oct. 31, 2007, the changes to the rules of practice in the claims and continuation final rules did not go into effect on Nov. 1, 2007.]
	o It is permissible to define an invention by using an independent form claim regardless of whether or not the invention defined in the independent form claim is identical with the invention defined in any other claim.	o According to these definitions, at least, if an independent claim relates to a steering wheel, then a claim formulated as "A vehicle having a steering wheel as in claim ..." would be a dependent claim. Other formulations such as "Use of a steering wheel as set out in	o A dependent claim must also be presented as a single sentence and have a preamble, transitional phrase and a body. The dependent claim may refer back to a single claim or to multiple claims. (37 CPR 1.75(c)). However, in the USPTO practice, multiple

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o Dependent form claims may be utilized to simplify the statements of claims by avoiding repetition of the same expressions and phrases. It is possible to define an invention by use of a dependent form claim regardless of whether or not the invention defined in the dependent form claim is identical with the invention defined in the claims referred to. o Claims may be written in dependent form to simplify the statements of claims by making reference to other claims, when writing claims which substitute a part of the matters defining invention of other preceding claims or when writing claims in a different category from that of other preceding claims, provided that the statements of the claims do not become unclear. o Multiple dependent form claims are claims defined by making reference to two or more claims (regardless of independent or dependent), and are utilized in simplifying the	Claim 1 in a vehicle ..." are also acceptable, although the change of category (from apparatus to use) has automatically made the latter claim an independent claim. o Dependent claims must, preferably at the beginning, refer back to the claim on which they depend. A dependent claim may also refer back to more than one previous claim which may be dependent or independent claim. o A claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 43(4) (Guidelines, C-III, 3.8).	dependent claims may refer back to other claims only in the alternative and may not depend, either directly or indirectly, upon any other multiple dependent claim. These two limitations are made to avoid confusion in determining how many claims are actually being referred to, and further, what the scope is of the multiple dependent claim. Improperly presented multiple dependent claims are objected to under 37 CPR 1.75(c) and are generally not treated on their merits until applicant places them in proper form. (MPEP 608.01(n)).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	statements of the claim. (Examination Guidelines Part I Chapter 1. Section 2.2.4.2 (1)(2))		
	o If a multiple dependent form claim refers to two or more claims in non-alternative form or if it does not impose an identical technical limitation on the respective claims referred to, it does not comply with the instruction on claiming practice which is provided in Note 14d of Form 29 of Regulations under Patent Act. This instruction, however, is not one of the legal requirements provided in the Act as a basis of a decision of refusal. Therefore, mere non-compliance with the instruction does not constitute a reason for refusal of an application. On the other hand, such a case as Example 1 or 2 should be determined as violating Article 36(6)(ii) because it makes a claimed invention unclear. Example 1: The claimed invention becomes unclear due to non-alternative reference to		o A dependent claim is construed to include all the limitations of the claim which is incorporated by reference. A multiple dependent claim is construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered (37 CPR 1.75(c)). o Effective November 1, 2007, 37 CFR 1.75(b) has been amended to state that a claim that refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim for purposes of 37 CFR 1.75(b) and for fee calculation purposes. A claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for purposes of 37 CFR 1.75(b) and for fee calculation purposes. [Note: In view of the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	other claims. Example 2: The category of the claimed invention becomes unclear due to the reference being made to claims of different subjects (categories), although an identical technical limitation is imposed on the claims referred to. (Examination Guidelines Part I Chapter 1. Section 2.2.4.2 (3))		preliminary injunction issued by the U.S. District Court for the Eastern District of VA on Oct. 31, 2007, the changes to the rules of practice in the claims and continuation final rules did not go into effect on Nov. 1, 2007.]
(e) Arrangement of claims	o Statements of the claim under Article 36(6)(iv) of the Patent Act which are to be in accordance with the Ordinance of the Ministry of Economy, Trade and Industry shall be as provided in each of the following items: (i) for each claim, the statements shall start on a new line with one number being assigned thereto; (ii) claims shall be numbered consecutively; (iii) in the statements in a claim, reference to other claims shall be made by the numbers assigned thereto; (iv) when a claim refers to another claim, the claim shall not precede the other claim to	o The claims are numbered consecutively in Arabic numerals (Rule 43(5)). When the claims are for different categories there is no obligation to start with one particular category or another although the order in which claims are presented may have some procedural effect in cases of lack of unity under Rule 44. The applicant is free to choose the arrangement of independent claims he prefers provided this does not lead to objections on the ground of lack of clarity and conciseness.	o The USPTO prefers applicant to arrange the claims in order of scope, so that the first claim presented is the broadest and the last, the most detailed. o Dependent claims should be arranged closest to the claim or claims from which they depend. Where separate species are claimed, the claims of like species should be grouped together where possible. (This provision may not be practical or possible where several species depend from the same generic claim.) Similarly, product and process claims should be separately grouped (MPEP 608.01(n)).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	which it refers. (Article 24-3 of Regulations under the Patent Act, Form 29-2)		
		o There is also no legal requirement that the first claim should be the broadest. o Dependent claims have to be grouped together in the most suitable way for the understanding and clarity of the set of claims as required by Rule 43(4) whose last sentence reads: "All dependent claims referring back to a singly previous claim, and all dependent claims referring back to several previous claims, shall be grouped together to the extent and in the most	o At the time of allowance, the examiner reviews the claim numbering and may renumber the claims by an examiner's amendment, presenting the claims in order of scope and near the claim from which they depend. See 37 CFR 1.126 and MPEP 1302.01.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		appropriate way possible".	
(3) Contents of claims			
(a) Indication of technical features of the invention	o The scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent. In such case, an invention specified by a statement in one claim may be the same invention specified by a statement in another claim. (Article 36 (5) of the Patent Act)	o Rule 43(1) reads: "the claims shall define the matter for which protection is sought in terms of the technical features of the invention" o An independent claim should contain all the technical features essential to the performance of the inventions the claim is otherwise held to be obscure (Article 84 in combination with Rule 43 (1) and (3)).	o It should be noted that claims in a U.S. patent application are evaluated in terms of the limitations presented. The phrase "technical features" is not a phrase of art for U.S. claiming practice.
			o 35 U.S.C. 112 permits applicant to claim the subject matter "which the applicant regards as his invention". 35 U.S.C. 112, second paragraph. An applicant may disclose in the specification many features, both technical and non-technical, of an invention, but may submit a claim of a scope that is different than the scope of the sum of all of the disclosed features. An applicant by submitting such a claim, ipso facto, indicates

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			what he believes to be his/her invention.
			o The U.S. examiner does not determine what he/she, the examiner, believes to be the invention after reading the specification. The U.S. examiner may not require that an "essential technical feature" be added to the claim merely because such a feature was disclosed as having a certain relationship to the claimed invention. U.S. case law has consistently held the claims define that which the applicant regards as his/her invention.
(b) Indication of non-technical matters	o If non-technical matter is stated in a claim as a whole as a result of existence of such statements as sales area or distributors, the description of the claims is considered not to comply with the requirements of Article 36(6)(ii) of the Patent Act. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (2) ⑤)	o As an example the Guidelines (C-III, 2.1) cite commercial advantages as a non-technical matter which should not be contained in the claims. o However, mentioning results or effects of technical features is allowable.	o The phrases "non-technical matters" or "non-technical features" are not phrases of art for U.S. claiming practice.
			o 35 U.S.C. 112 permits applicant to claim the subject matter "which the applicant regards

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			as his invention". 35 U.S.C. 112, second paragraph. Upon filing an application, applicant submits a claim containing limitations. By submitting a claim, applicant has designated the limitations to represent what he/she regards as his/her invention. U.S. law and/or practice do not require the applicant to identify the limitations in terms of technical features and non-technical features.
(c) Indication of purpose	o There is no requirement to describe the purpose.	o When the claim is for a physical entity (product, apparatus) it might be worthwhile to indicate the purpose of it. This is generally clear in itself when the claim is for a method. o The indication of the purpose in the case of a physical entity may have a limiting effect on the scope of the patented matter, allowing the exclusion of an otherwise pertinent prior disclosed document (Guidelines C-III, 4.13).	o U.S. law does not recognize the word "purpose" as a term of art. U.S. law does not state that the purpose must be included as a limitation in a claim. o The U.S. examiner in evaluating the limitations in the claim, does not read into the limitations a "purpose". The examiner will not read into the claim any phrase as a limitation that is not present in the claim and certainly not an "intended use" or an "object of the invention" that has been described in the specification and which may be construed by some as the "purpose" of the invention. For

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			the examiner to do such, would mean the examiner would be determining what the invention is, and not the applicant, contrary to U.S. case law.
(d) Limitation on function	o When the claim includes matters defining a product by its function or characteristics, etc., the scope of the invention cannot necessarily be clear and an invention for which a patent is sought may not be clearly identified. o Where a claim includes the definition of a product by its function or characteristics, etc., if a person skilled in the art can conceive a concrete product with such function or characteristics, etc., by taking into consideration the common general knowledge as of the filing, the concrete matters, which are clue for the judgment of requirements for patentability such as novelty and inventive step, etc., and for understanding the technical	o At the moment the EPO sees no special aspect of the claim drafting practice which would fall under this item and not be more precisely covered by (c) above or (e) below.	o In USPTO practice there is no prohibition against the inclusion of functional language in a claim. Functional language is used to describe what the invention does. This is in contrast to claiming the invention by its elements. Functional language in the claim is not disregarded in evaluating patentability. o However, functional language is objectionable in a claim when (1) the language is not precise and definite in defining the invention and (2) the language has a scope of protection beyond what is disclosed in the specification.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	scope of the patented invention, can be understood. Accordingly, the scope of the invention is clear so that the invention for which a patent is sought is clearly identified. o On the contrary, when a person skilled in the art cannot conceive a concrete product with such function or characteristics, etc., even by taking into consideration the common general knowledge as of the filing, since the concrete matters pertaining to the invention cannot be understood, the scope of the invention usually cannot be deemed clear. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (6) ①)		
(e) Definition by function	o When the claim includes matters defining a product by its function or characteristics, etc., the scope of the invention cannot necessarily be clear and an invention for which a patent is sought may not be clearly identified. o Where a claim includes the definition of a product by its function or characteristics, etc.,	o Functional terms used in claims are in fact considered as being technical features expressed in a different way. It follows that there would be no reason to refuse claims, as a matter of principle, just because some of the characteristics are expressed in functional terms. o The Guidelines (C-III. 2.1) state that	o Functional language describes the invention by what the invention does and not by its elements. There is no prohibition in U.S. law against the use of functional language in claims. o In addition, functional language may be considered as structural elements when coupled with an introductory "means" phrase,

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	if a person skilled in the art can conceive a concrete product with such function or characteristics, etc., by taking into consideration the common general knowledge as of the filing, the concrete matters, which are clue for the judgment of requirements for patentability such as novelty and inventive step, etc., and for understanding the technical scope of the patented invention, can be understood. Accordingly, the scope of the invention is clear so that the invention for which a patent is sought is clearly identified. o On the contrary, when a person skilled in the art cannot conceive a concrete product with such function or characteristics, etc., even by taking into consideration the common general knowledge as of the filing, since the concrete matters pertaining to the invention cannot be understood, the scope of the invention usually cannot be deemed clear. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (6) ①)	"Functional limitations may be included provided that a skilled man would have no difficulty in providing some means of performing this function without exercising inventive skill".	which is known in USPTO practice as a means plus function limitation (35 U.S.C. 112, 6th paragraph).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o In a basic Board of Appeal Decision functional features are said to be permissible in a claim only if, "from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the invention, and if these features provide instructions which are sufficiently clear for the expert to reduce them to practice without undue burden, if necessary with reasonable experiments".	o 35 U.S.C. 112, paragraph 6 provides "An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." o Even though the claim may be presented in means plus function format, the claim must comply with the requirements of the second paragraph of 35 U.S.C. 112 and not be vague and indefinite.
(f) Definition of terms	o Where the statement in a claim are deemed unclear by itself, the examiner should examine whether a term in the claim is defined or explained in the specification and drawings, and should evaluate whether such definition or explanation, if any, makes the claim statements clear by considering the common general knowledge as of the filing. If the examiner deems that an invention can be	o Claims should normally be clear from the wording of the claim alone giving the words the meaning they normally have in the relevant art. o When a word in a claim is given a special meaning, this should be made clear as far as possible already in the claim itself. One of the reasons for this is that only the claims will be published in the three official	o In drafting language for the specification and claims, applicant is permitted to be his/her own lexicographer and thereby choose and define the terms that describe the invention. This is necessary since new expressions must be developed for the ever changing technology and in order to communicate the invention. o Words are given their ordinary and

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	clearly identified as a result of this evaluation, the requirement of Article 36(6)(ii) is met. (Examination Guidelines Part I Chapter 1. Section 2.2.2 (4))	languages of the EPO (Guidelines C-III, 4.2). o There are however rare exceptions where the complete definition of a particular term, e.g. a parameter, used in a claim, will only be found in the description, for instance where its introduction into the claim would lead to lack of clarity or conciseness .	customary meaning unless the specification defines the term differently. See MPEP 2111.01. A term may not be given a meaning repugnant to the usual meaning of the term. Broad terms are not objectionable merely because they are broad if the terms are properly supported in the specification and define the subject matter.
	o As to the technical terms such as microorganisms, substances with foreign names, the meaning of which is difficult to be fully expressed in Japanese, the name thereof in Japanese is followed by words in the original language in parentheses. (Article 24-4 of Regulations under the Patent Act, Form 29-2)		o Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same element should not be permitted. o While an applicant is not limited to the nomenclature used in the application as filed, when a new term is added to the claims the appropriate addition is to be made to the specification provided the new term is not new matter. (MPEP 608.01(o)).

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(g) Description in alternative form	o When there are some expressions in claims which describe optionally added items or selective items, along with words such as "when desired," "if necessary," etc.. , there are some occasions where the description of the claims is not clear. o Such expressions would leave unclear the condition on which of the optionally added or selective items are chosen, thus allow the claim statements to be interpreted in many ways. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (5) ④)	o No provisions of the EPC especially prevent the claim from containing alternatives, provided that the basic criterion of clarity is satisfied. Alternative forms in a single claim are even often a way to keep the set of claims as concise as possible. o This is especially the case in chemistry with large families of compounds which are covered by the so-called Markush grouping. A Markush claim is nothing more than a way to have a large number of alternatives in one claim (see also (2) (b) above).	o Alternative expressions are permitted in a claim provided that the expressed elements are basically equivalents for the use in the invention. The claim still must be clear and definite so that the alternative expression does not present an uncertainty or an ambiguity with respect to the claim scope or breadth. o In addition, a Markush group provides for alternative expressions in a claim. While a Markush group is primarily used in chemical practice, there is no prohibition as to its use in mechanical or electrical applications. A Markush group is used where there is no commonly accepted generic expression which is commensurate in scope with the field which applicant desires to cover.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o The presence of alternatives that are simply different ways of referring to the same feature are held to leave a claim obscure and are not taken to be true alternatives. Thus, reference to a particular feature as "a rod or wire" would need to be clarified. If only one kind of structure for the feature were intended, then only one term would be allowed.	
		o In certain circumstances, the grouping of alternatives in a single claim could be considered as a way of escaping the payment of additional fees for claims over the number of 10 in one patent application (Rule 45). The EPO approach there is to avoid being too formal and to accept alternatives provided that grouping does not raise problems concerning clarity.	o The materials set forth in a Markush group ordinarily must belong to a recognized physical or chemical class or to an art recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by the consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. (MPEP 803.02). For the structure of Markush claims see Section 3. (2) (b).
(h) Use of ambiguous terms (e.g. definition by terms indicating extent)	o When the scope of the invention is unclear as a result of the following expression, there are some occasions where the description of the claims is not clear: ①Negative expressions such as “except...“ and “not...“ in claims ②Expressions using a numerical limitation which only indicates either a minimum or a maximum such as “more than...“ and “less	o By their very nature ambiguous terms do raise a problem of clarity and examiners are normally required to object against them. The Guidelines (C-III, 4.6) make it clear that "... an unclear tern cannot be allowed in a claim if the term is essential having regard to the invention. Equally an unclear term cannot be used by the applicant to distinguish his invention from the prior art".	o In USPTO practice, terms indicating extent do not automatically render a claim invalid due to indefiniteness under 35 U.S.C. 112. Examples of these terms are "substantially", "relatively" and "closely". When a word of degree is used with a claim limitation, the examiner must determine if the specification provides some standard for measuring that degree and if one skilled in the art can

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	than..." ③Expressions where the standard or degree of comparison is unclear such as "with slightly greater specific gravity," "much bigger," "low temperature," "high temperature," "hard to slip," "easy to slip" or where the meaning of the term is unclear. ④Expressions including such words as "especially," "for example," "etc.," "desirably," and "suitably." ⑤A numerical limitation which includes zero (0) such as "from 0% to 10%." ⑥A statement of a claim is made by a reference to the detailed description of the invention or drawings, and as a result, the extent of the invention for which a patent is sought is unclear. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (5))	o It is recommended not to use a term like "thin", "wide", or "strong" in a claim unless it has in the art a particular meaning as for instance "high frequency" in radio-communication. Such terms cannot be clear enough to be a differentiating feature of the invention. o Particular attention is also required whenever words such as "about", or "approximately" are used, even if their use is not, depending on the case, strictly prohibited (Guidelines C-III, 4.7).	determine whether a product or process falls within the language of a claim. See MPEP 2173.05(b).
		o Expressions like "preferably", "for example", "such as", or "more particularly" have no limiting effect and could simply introduce ambiguity (Guidelines C-III, 4.9).	

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(i) Claims attempting to define the invention by objectives to be attained	o Where the claim includes the definition of a product by the result to be achieved, there may be cases where concrete products which can obtain such result can not be conceived. When a certain concrete means which can obtain such result is disclosed in the specification or drawings and it is also recognized that only the said concrete means is substantially disclosed, the scope of the invention is deemed unclear. In such cases, it usually cannot be said that the invention disclosed in the specification or drawings can not be properly identified unless defining the product by the said result to be achieved. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (6)③(ii))	o The claims should define, in term of technical characteristics, the way in which the result is obtained. o This precludes the invention from being totally defined by the objective to be reached. o However, in combination with other features of a technical nature, the use of a result to be achieved as one of the characteristics of the invention may be allowed (Guidelines C-III, 4.10). It has then the status of a functional definition (see (3) (e) above).	o U.S. law does not require the claim to define the objectives to be attained or prohibit the claim from doing so. U.S. law would permit the objective to be recited in the claim but would evaluate the claim to ensure that the claim is definite in defining the invention and that the language used does not provide a scope of protection beyond what is disclosed in the specification.
		o A prerequisite for accepting such a wording in claims is that no other way exists to define the invention and that the result be directly and positively verified by tests or procedures adequately specified in the description and involving nothing more than trial and error.	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(j) Definition using chemical or mathematical equations or formulas	o Chemical formula etc. in claims are described in the following manners: when chemical formula is described, a sequence number like “[Chem. 1], [Chem. 2]” is referred before the chemical formula, when numerical formula is described, a sequence number like “[Math. 1], [Math. 2]” is referred before the numerical formula, when table is described, a sequence number like “[Table 1], [Table 2]” is refereed before the table, referring to a sequence number in the described order. (Form 29-2)	o Rule 49(9) reads: "the description, the claims and the abstract may contain chemical or mathematical formulae ...". The claims may contain tables only if their subject-matter makes the use of tables desirable. o The examiners are instructed not to object to the use of tables in claims where this form is convenient (Guidelines C-III, 2.4).	o There is no prohibition against the use of chemical or mathematical equations and formulas in a claim to define the invention. o A chemical formula defining a chemical composition or compound comes within eligible subject matter of Section 101. o A mathematical equation or formula, per se, is not patentable subject matter. It is considered an algorithm and does not come within the subject matter of 35 USC 101, i.e. "any new and useful process, machine manufacture or composition of matter or any new and useful improvement thereof". See MPEP 2106.02.
			Inventions involving mathematical equation or formula must fall within one of the stated categories of Section 101 in order to be eligible subject matter. The examiner analyzes a claim to determine if a mathematical algorithm, formula or equation is directly or indirectly recited. If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			of the foregoing, the acts are not being applied to appropriate subject matter. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process. Claims define nonstatutory processes if they consist solely of mathematical operations without some claimed practical application, or simply manipulate abstract ideas without some claimed practical application.
			o Where various terms in the mathematical or chemical equations or formulas has been defined in the specification, there is no requirement to repeat the definition of each term in the body of the claim.
(k) Devices or objects with limitations on their usage	o In case where a claim directed to a use invention explicitly includes a statement to mean a use of a product and the statement does not express a specific use but a general use, it should not be deemed a violation of Article 36(6)(ii) merely because the statement	o Claims such as "Apparatus for a certain use" or "Product for use as ..." are construed as meaning that the apparatus or the product claimed are suitable for the indicated use. o When considering whether or not such a	o 35 U.S.C. 112, second paragraph permits the applicant to claim subject matter which he regards to be his invention. Applicant may include negative limitations in the claims provided such limitations do not result in a failure to point out the invention in the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	expresses a general use (i.e., merely because the scope of the claim is relatively broad) unless the expression makes unclear the invention for which a patent is sought. (For example, it should not be deemed a violation of Article 36(6)(ii) merely because the statement expresses not a “pharmaceutical/agrochemical substance for disease X comprising...” but ”a pharmaceutical/ agrochemical substance comprising...”) The detailed description of the invention, however, shall comply with the provision of Article 36(4)(i). Where a claim is directed to a composition and dose not include any statement to define the use of the composition or the property of the composition, it shall not be deemed a violation of Article 36(6)(ii) merely because the claim does not include any definition by the use or property of the composition. (Examination Guidelines Part I Chapter 1. Section 2.2.2.2)	claim is anticipated by a prior disclosure, such a disclosure should be for an apparatus or a product which is also suitable - even if not explicitly stated - for the same use. o However the protection conferred by the claim is not interpreted as being limited to the stated use. On the contrary, the claim is interpreted as being for the apparatus or product per se (Guidellines C-III, 4.13). An exception to this principle applies in the field of medical treatment. According to Art. 54(4), where the substance or composition is known, it may only be patented for use in surgery, therapy or diagnostic methods practised on the human or animal body ("first medical use") if the known substance or composition was not previously disclosed for use in these methods. A claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods should be in a form such as: "Substance or composition X" followed by the	manner contemplated by 35 U.S.C. 112 (See MPEP 2173.05(i)). o In a chemical composition, product or apparatus claim an applicant may also recite an intended use of the composition, product or apparatus; however, the weight to be given to such a limitation in distinguishing over the prior art relating to the composition, product or apparatus will be determined on a case by case basis.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		indication of the use, for instance "... for use as a medicament", "... as an antibacterial agent " or "... for curing disease Y". Where a substance or composition is already known to have been used in a "first medical use", it may still be patentable under Art. 54(5) for any second or further use in a method according to Art. 53(c), provided that said use is novel and inventive. Art. 54(4) and (5) thus provide for an exception from the general principle that product claims can only be obtained for (absolutely) novel products. However, this does not mean that product claims for the first and further medical uses need not fulfill all other requirements of patentability, especially that of inventive step. A claim in the form "Use of substance or composition X for the treatment of disease Y..." will be regarded as relating to a method for treatment explicitly excluded from	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		patentability under Art. 53(c) and therefore will not be accepted. For more details on how these new regulations will be applied, see Guidelines C-IV, 4.8.	
		o The indication of the intended use in an apparatus or a product claim may result in a lack of clarity (Article 84) and should then be objected to accordingly.	
		Examiners are instructed to object against claims such as: "Apparatus for carrying out the process of Claim 1" which does not explicitly set out the technical features of the apparatus.	

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
(1) Dependence on references to description of the invention or to drawings	o There are some cases where a claim is not clear if a statement of the claim is made by a reference to the detailed description of the invention or drawings, and as a result, the extent of the invention for which a patent is sought is unclear. Example 1: A claim which includes such statement made by a reference as "an automatic drill machine as shown in Figure 1." (It is inadequate to refer to drawings because drawings generally have ambiguous meanings and could be interpreted 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 detailed description of the invention or drawings. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1(5)⑥)	o The direct reference in claims to the description or drawings is generally not allowed (Rule 43(6)). o The Guidelines (C-III, 4.17) give two examples of cases where it may exceptionally be accepted to refer to the description or drawings. The first one is an invention involving some peculiar shape, illustrated by drawings which could not be readily defined in words or by a mathematical formula in the claims. The other one is for a chemical product some of whose features can be defined only by means of graphs or diagrams.	o Claims are construed in light of the specification but limitations from the specification which are not written into the claims are not considered to be present therein. The words used in the claims will be given their ordinary and customary meaning unless a definition of the term that is different from its ordinary and customary meaning is clearly set forth in the specification. While the claims are construed in light of the specification, it does not mean that the claims incorporate all the disclosed features of the specification which are not recited in the claims. See MPEP 2111 and 2111.01.
	o Note that, even by referring to the detailed description of the invention or drawings, an invention can be stated clearly in a claim as in the following case. Example: In an invention related to an alloy,	o Rule 43(7) encourages the use in claims of reference signs to features of the drawings, which help understand the wording of the claim. However, adding text to reference signs in parentheses in the claims should be	o If non-claimed features in the specification were required to be read into the claims, or if claims were to be limited to the specific embodiment disclosed in the specification, an applicant, regardless of the prior art, could

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	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. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1(5)⑥)	avoided as such indications may be understood as limiting features (C-III, 4.19).	not claim more broadly than that specific embodiment disclosed in the specification. Under USPTO patent law, applicant is permitted to claim what he regards to be his invention and to draft the claims as broadly as the prior art permits provided the specification is enabling for the scope of the claims presented.
			o Drawings may be used in the same manner to interpret the claims as the specification.
(m) Others		o Under this item the EPO suggest the consideration of the allowability of disclaimers in claims. The purpose of a disclaimer is to limit the scope of a claim, expressly excluding from it an element defined by its technical features. This technique of the disclaimer is very often used in chemistry to exclude elements which do not satisfy all the criteria for patentability, but its use is not in any way limited to chemistry. According to the EPO practice and as confirmed by a Board of Appeal Decision a disclaimer may however be used	o No other comments.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		only where there is no better way to define the subject-matter of the invention using positive technical features (Guidelines, C-III, 4.20).	
(4) Support in description of the invention (extent of disclosure in the description and drawings vs. broadness of claims, e.g. the relationship between the scopes of working examples and claims, or the extent to which addition of working examples is permitted)		o According to Article 84 EPC, the "claims shall be supported by the description". This requirement is a substantive requirement and not merely a matter of verbal consistency with the broadest statement of the invention sometimes set out in the introductory part of the description (see 2. (3) (iv) above). o Most patent applications involve a generalisation of what the inventors have actually carried out. To allow such a generalisation in the description is an accepted practice which is then reflected in the wording of the claims. The key issue is: how broad may the generalisation be? This can only be decided on a case by case basis.	o 35 U.S.C. 112, first paragraph requires "that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". See MPEP 2164.08. o This does not imply that the claims must be strictly limited to what has been explicitly demonstrated in the specification to be enabling (see section 3. (4) (a)). There is no requirement in USPTO practice that the claims be limited to working examples. See Section 3. (3) (1). o In determining the scope of the invention that is sought to be patented the claims will not be read in a vacuum but in light of the specification and the teachings of the prior art. (See Section 3. (3) (f)).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o As a general rule "A fair statement of claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the applicant of a just reward for the disclosure of his invention" (Guidelines C-III 6.2).	o However, the claims will be given "the broadest reasonable interpretation consistent with the specification during the examination ... since the applicant may then amend his claims, the thought being to reduce the possibility that, after the patent is granted, the claims may be interpreted as giving broader coverage than is justified".
(a) Undue breadth			
- Disclosure problem	o An invention stated in any claim shall not extend beyond the scope defined in a detailed description of the invention. (Article 36(6)(i) of the Patent Act) (Examination Guidelines Part I Chapter 1. Section 2.2.1(3))	o A claim, provided it contains technical features, can only be considered as being unduly broad by comparison with the description. The question is one of adequate support by the description for the scope of the claim. This support should be of a technical character and not be merely a vague statement without technical content.	o A claim that is drafted unduly broad vis-a-vis the actual invention may be rejectable under three basis: 1) Claims may be broader than the prior art will permit. 2) If the claims encompass subject matter that the inventor does not in fact regard as part of his invention the claims would be rejectable under 35 U.S.C. 112, second paragraph which requires that an applicant particularly point out and distinctly claim the subject matter which the applicant regards as his invention. 3) Where a claim encompasses material for which the specification is not enabling along

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			with material for which the specification is enabling the claim would be rejectable under 35 U.S.C. 112, first paragraph.
	o Typical cases exhibiting nonconformity to the provision of Article 36 (6) (i) are presented below: (i) the matter corresponding to claims is neither stated nor implied in a detailed description of the invention, (ii) the terms used in claims and those used in a detailed description of the invention are inconsistent, and as a result, the relationship between a claim and a detailed description of the invention is unclear, (iii) the matter disclosed in a detailed description of the invention cannot be extended and generalized to the scope of the matter in a claimed invention even if taking into account the common general knowledge as of the filing, or (iv) a means for solving the problems described in a detailed description of the invention is not reflected in the claims, and as		o All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enable to make and use the entire scope of the claimed invention without undue experimentation. See MPEP 2164.08.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	a result, a patent beyond the scope described in the detailed description is consequently claimed. (Examination Guidelines Part I Chapter 1. Section 2.2.1(3))		
			o The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. See MPEP 2164.03. o Examples of enablement issues in chemical cases, see MPEP 2164.06(b). o Examples of enablement issues in computer

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			programming cases, see MPEP 2164.06(c).
			o In order to make a rejection under 35 U.S.C. 112, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. See MPEP 2164.04.
- Claims reading on inoperative subject matter	o When matters disclosed in a detailed description of the invention cannot be extended or generalized to the scope of matters in a claimed invention even if taking into account common general knowledge as of the filing, the description of the claims is considered not to comply with the requirements of Article 36(6)(i) of the Patent Act. (Examination Guidelines Part I Chapter 1. Section 2.2.1.1(3))	o As a general rule (Guidelines C-III, 6.3), "a claim should be regarded as supported by the description unless exceptionally there are well-founded reasons for believing that the skilled man would be unable, on the basis of the information given in the application as filed, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis". This means that the burden is on the examiner to establish why the result expected could not be reached for a certain part of the subject-matter claimed. However, once the examiner has set out a reasoned case that a claim is	o The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. See MPEP 2164.08(b). o Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		not supported over the whole of its breath, the onus of demonstrating the contrary lies with the applicant.	
		o Addition of working examples in support of a claim is not allowed to the description since it would infringe Article 123 (2) as being new matter. The examples are however taken into consideration when considering the operability of the invention, they are kept in the file and a special mention of this fact will be printed on the cover page of the granted patent.	o Claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.
- Relationship between working examples and claims	o Extension or Generalization based on one or more specific embodiments in a detailed description of the invention is permissible in a claim. The maximum extent of extension or generalization must not go beyond the scope of matters described in a detailed description of the invention. Because the maximum extent varies with characteristics of the technical field, the proper scope shall be set for each application. (Examination Guidelines Part I Chapter 1. Section 2.2.1 (3) (ii))	o According to Article 84 EPC the Claims, which define the matter for which protection is sought have to be supported by the description. o Examples are a part of the description. It is however possible for the applicant to provide further examples to support its assertions while the case is pending before the examining/ opposition divisions or the Boards of Appeal. o There is no rule, guideline or instruction	o In USPTO practice, the claims are interpreted in light of the disclosure. However, the statement does not mean that the disclosure is used to limit the scope of the claims. Examples that are presented in the disclosure are just that - examples. Examples are used as a guide to instruct the ordinary person skilled in the art in the making or in the operation of the invention. The examples are not read into the claims as limitations which would limit the scope of the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		which, in the EPO, would provide the examiners with guidance on how broad Claims may be for instance in relation to the kind and number of working examples. The principle is that the description has to give sufficient information to third parties allowing the subject-matter claimed to be carried out by the man skilled in the art.	coverage. Only the claim limitations are used to measure the extent of the coverage of the invention. A product or process that is not the same as the examples explicitly set forth in the disclosure would still infringe the claimed invention if the product or process reads on the literal wording of the claim.
	o In order for the statement of claims to meet the requirements of Article 36(6)(i) of the Patent Act, it is reasonable to interpret that a detailed description of the invention is required to be described in such a manner that a person skilled in the art can recognize that the invention has desired effect (property) within the scope which the formula described in the claim in light of the common general knowledge at the time of filing. (Intellectual property High Court Judgment 2005(Gyo-Ke) 10042)	o Examples help to provide this information, although they might in particular circumstances not be necessary at all. The EPO might then grant a patent with no example and refuse another one containing a great deal of examples on the ground of lack of a sufficient disclosure. Rule 42 EPC, dealing with the content of the description, in no way makes examples mandatory. Its paragraph (e) indicates: (The description shall:) describe in detail at least one way of carrying out the invention claimed using examples where appropriate ...	
		o The Guidelines for examination in the EPO (C-II, 4.9) draw attention to the fact that	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		"regard must be had to the facts of the particular case. There are some instances where even a very broad field is sufficiently exemplified by a limited number of examples or even one example".	
(b) Broadening claims	o After an amendment is done, if matter defining an invention in claims comes to be outside the scope of matters described in a description, etc. as filed, the amendment is not acceptable. (Examination Guidelines Part III(AMENDMENT OF SPECIFICATION AND DRAWINGS) Chapter 1.(New Matter) Section 4.1) o It is prohibited to make an amendment whereby inventions, of which patentability has been determined in a notice of reasons for refusal, among claimed inventions prior to the amendment, and inventions amended after the notice of reasons for refusal is given do not meet the requirements for unity of invention because they do not have any same or corresponding special technical feature.	o During examination, applicants are free to change the scope of their claims until they have replied to the first communication from the Office as set out below (Rule 137(2)). o Amendment of the claims can only take place after the Search Report has been received by the applicant (Rule 137(1)). Before receipt of the first communication from the Examining Division the application, in particular the claims, may be amended (Rule 137(2)). o After receipt of the first communication the applicant may amend the claims once, of his own volition, provided this be made at the same time as the reply to the communication. Further amendments may be refused by the Examining Division (Rule 137(3)). Guidance on how to exercise the	o Under USPTO practice, generally, an applicant may claim his invention as broad as the prior art and his disclosure will allow and the applicant may broaden any claim during prosecution of the application. However, under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. See MPEP 2163, subsection I.B. "Broadening a claim does not add new matter to the disclosure" so long as the disclosure as originally filed supports the amended claim.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	(Article 17-2 (4) of the Patent Act , Examination Guidelines Part Ⅲ (AMENDMENT OF SPECIFICATION AND DRAWINGS) Chapter 2.(Amendment that Changes a Special Technical Feature of an Invention) Section 3.)	discretion given in this respect is contained in Guidelines C-VI, 4.7 et seq.	
	o The amendment of the scope of claims after the final notice of reasons for refusal shall be limited to those for the following purposes; (i) the deletion of a claim or claims as provided in Article 36(5); (ii) restriction of the scope of claims (limited to the cases where the restriction is to restrict matters required to identify the invention stated in a claim or claims under Article 36(5), and the industrial applicability and the problem to be solved of the invention stated in the said claim or claims prior to the amendment are identical with those after the amendment); (iii) the correction of errors; and (iv) the clarification of an ambiguous	o However, according to Article 123 (2) any broadening of the claims should not extend beyond the content of the application as filed. Where the application as filed contains claims for subject-matter not mentioned in the description, the wording of these claims may be transferred to the description without infringing Article 123 (2) (Guidelines C-III, 6.6).	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	statement (limited to the matters stated in the reasons for refusal in the notice of reasons for refusal). (Article 17-2 (5) of the Patent Act)		
		o In opposition proceedings, amendments to the claims of the granted patent may be allowed only if these do not extend the protection conferred (Article 123 (3)).	
(c) Narrowing and sub-generic claims	o See (4)(b) above. o In JPO, if matter, which is not described in a description, etc. as filed, is singled out, as a result of an amendment to be conceptually specific (for example, matter defining an invention in claims is added), the amendment cannot be construed to be done within the scope of matters described in a description, etc. as filed. (Examination Guidelines Part III(AMENDMENT OF SPECIFICATION AND DRAWINGS) Chapter 1.(New Matter) Section 4.2 (1)①)	o sub-generic claims can always be filed under the same principles as set out above in (4) (b), provided there is support for them in the description. It might of course occur that the generic claim is supported by the description although direct support is lacking for a particular sub-generic claim.	o Under USPTO practice, an applicant may narrow the claims during prosecution to avoid the prior art (or for any other purpose). o In chemical cases and in cases involving compositions of matter, the disclosure of a species in a cited reference is sufficient to prevent a later applicant from obtaining a generic claim. MPEP 715.03.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			However, in the particular instance wherein a genus and several species are originally believed by an applicant to be patentable and wherein it is later determined during examination that at least one species and therefore the genus are unpatentable over the prior art the applicant may cancel the genus and the known species while continuing to claim the other species which are not taught by the prior art. o In accordance with the above USPTO practice an applicant may present both generic and sub-generic claims.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			A particular example involves Markush practice wherein a generic-type claim may be expressed as a group consisting of certain specified materials. Section 3. (3) (g). It is permitted to use Markush claims of diminishing scope unless the claims are rendered indefinite and to present a true genus claim in addition to Markush claims. MPEP 2173.05(h), subsection I.
4. Drawings			
(1) Substantive questions (e.g. status of drawings as part of the disclosure)	o The description, scope of claims, drawings (Where required), and abstract shall be attached to the application. (Article 36 (2) of the Patent Act)	o The drawings are regarded as a part of the disclosure. o Though the description is generally considered to provide the most important contribution to the sufficiency of the disclosure, the drawings (and the claims) may also help to ensure sufficiency. o Insofar as a precise feature is indisputably disclosed in a drawing, it can be the subject-matter of a claim, even if it was not referred to in the description or expressly indicated as important for the invention. o More generally, the purpose of the	o 35 U.S.C. 113 states that the applicant shall furnish a drawing where necessary for the understanding of the subject matter to be patented ... Drawings submitted after the filing date of the application may not be used (i) to overcome any insufficiency of the specification due to lack of an enabling disclosure or otherwise inadequate disclosure therein, or (ii) to supplement the original disclosure thereof for the purpose of interpretation of the scope of any claim. o An applicant for a patent is required by law to furnish a drawing whenever the nature of

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		drawings is to help in understanding the description (and, possibly, the claims) and in the interpretation of the claims.	the case admits of it; this drawing must be filed with the application. This includes practically all inventions except compositions of matter or processes, but a drawing may also be useful in the case of many processes.
	o The detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing. (Examination Guidelines Part I Chapter 1. Section 3.2 (1)) o The technical scope of a patented invention shall be determined based upon the statements in the claim attached to the application. (Article 70 (1) of the Patent Act) o In the case of the preceding paragraph, the meaning of each term used in the scope of claims shall be interpreted in consideration of the statements in the description and drawings attached to the application. (Article 70 (2) of		o Drawings filed with the application are considered to be part of the disclosure of the invention. The court in In re Berkman, 209 USPQ 45 (CCPA 1981) stated that the disclosure requirement set forth in 35 U.S.C. 112, first paragraph requires a written description of the invention, of the manner and process of making and using the invention and of the best mode contemplated by the inventor of carrying out his invention. The drawings may be used to satisfy the disclosure requirement but cannot eliminate the need for a specification.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	the Patent Act)		
(2) Formal requirements	o Drawings to be attached to a request shall be prepared in accordance with the Form 30 (Article 25 on Regulations under the Patent Act).	o The form of the drawings is dealt with extensively in Rule 46 . o In addition, the following requirements are to be noted: o The request for grant, the description, the claims and the abstract should not contain drawings (Rule 49(9)). o If the application contains drawings these should be referred to in the description and the latter should describe the figures in the drawings (Rule 42(d)). However, the references used in the drawings need not be listed.	o The standards for drawings are set forth in 37 CFR 1.84. o The drawings must show every feature of the invention specified in the claims. o Conventional features disclosed in the description and claims which are not essential for a proper understanding of the invention should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g. a labeled rectangular box). o The drawing is required by the rules to be in a particular form, that is, the size of the sheet on which the drawings is made, the type of paper, the margins, and other details relating to the making of the drawing. The Office no longer considers drawings as formal or informal. Drawings are either acceptable or

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			not acceptable. Drawings will be accepted by the Office of Initial Patent Examination if the drawings are readable, and reproducible for publication purposes. See MPEP 608.02(b). o The drawing must contain as many figures as may be necessary to show the invention.
(3) Photographs in lieu of drawings (i.e. their status, categories accepted, conditions of acceptance, etc.)	o Drawings shall be drawn in black explicitly and not to be deleted easily, according the method of drawing. Drawing shall also not to be colored. (Form 30) o A photograph may be adopted as a drawing, if the subject is difficult to be drawn by graphics, such as micrographs, X-ray photographs, and crystal structures. o Furthermore, a color photograph is not acceptable except that it is attached as a photograph for reference. (Formality Examination Manual 24.11)	o Photographs can only exceptionally be allowed. Colour photographs are not accepted. o They are allowed where drawings are not sufficient to illustrate the invention or where the photographs contain information which cannot be expressed in a different manner (e.g. microphotograph) (Guidelines C-II, 5.3).	o Photographs are not ordinarily permitted in utility and design application. The Office will accept photographs in utility and design applications if photographs are the only practicable medium for illustrating the claimed invention. See 37 CFR 1.84(b). o Black and white photographs submitted in lieu of ink drawings must comply with 37 CFR 1.84(b). Such photographs to be acceptable must be made on photographic paper having the following characteristics which are generally recognized in the photographic trade: double weight paper with a surface described as smooth with a white tint.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o Even in this case, however, those technical features which are essential must be distinguishable the on reproduction of photograph.	o If several photographs are used to make one sheet of drawings, the photographs must be contained (i.e., developed) on a single sheet. See MPEP 608.02, subsection VII. o Photographs may be treated as artifacts and maintained in an artifact folder when the patent application is in an Image File Wrapper (IFW) application, since the photographs may not be able to be accurately reproduced by scanning.
			o Limited use of color drawings or color photographs in utility and design patent applications is provided for in 37 CFR 1.84(a)(2) and (b)(2). Unless a petition is filed and granted, color drawings or color photographs will not be accepted in a utility or design patent applications. Applicant must file a petition with fee requesting acceptance of the color drawings or color photographs. Three sets of color drawings or color photographs must also be submitted. The petition is decided by a Supervisory Patent Examiner. See MPEP 608.02, subsection VIII.

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
5. Abstract	o Abstract shall be prepared in accordance with the Form 31. (Article 25-3 on Regulations under the Patent Act) o Abstract shall state a summary of the invention disclosed in the description, scope of claims or drawings, and the number referred to the figure which is the most suitable to contain in the Official Gazette. (Article 36 (7) of the Patent Act, Article 25-2 on Regulations under the Patent Act) o When the technical scope of the patented invention is defined, statements in the abstract attached to the application shall not be taken into consideration. (Article 70 (3) of the Patent Act)	o The abstract serves merely for use as technical information. It may not be taken into account for any other purpose, in particular not for the purpose of interpreting the scope of the protection sought nor for the purpose of distinguishing between interfering applications (Article 85). o The abstract should indicate the title of the invention. It should contain a concise summary of the disclosure as contained in the description, the claims and any drawings; the summary should indicate the technical field to which the invention pertains and be drafted in a way which allows the clear understanding of the technical problem, the gist of the solution of that problem through the invention and the principal use or uses of the invention. The abstract should, where applicable, contain the chemical formula which, among those contained in the application, best characterises the invention. It should not contain statements on the alleged merits or	o The abstract of the disclosure has been interpreted to be part of the specification for the purpose of compliance with the requirements of 35 U.S.C. 112, first paragraph. In re Armbruster, 185 USPQ 152 (CCPA 1975). o The requirement and guidelines for the abstract are set forth in 37 CPR 1.72(b) and MPEP 608.01(b) respectively. 37 CFR 1.72 (b) states: o A brief abstract of the technical disclosure in the specification must be set forth on a separate sheet, preferably following the claims under the heading "Abstract" or "Abstract of the Disclosure"...The purpose of the abstract is to enable the Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		value of the invention or on speculative aspects thereof.	
		o The abstract should be so drafted that it constitutes an efficient instrument for purposes of searching in the particular technical field. It should make it possible to assess whether a further consultation of the European patent application is needed. Further details concerning form and contents of the abstract are laid down in Rule 47.	o The content of an abstract should be such as to enable the reader, regardless of his familiarity with the patent documents to ascertain quickly the character of the subject matter covered by the technical disclosure.
		o The abstract filed by the applicant is only regarded as a suggestion and may be amended by the search examiner. In practice, such amendment is rare. o The final version of the abstract is established together with the search report. When doing so, the examiner should check it against the	o The abstract should consist of a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. o With regard to chemical patents, for compounds or compositions, the general nature of the compound or composition should be given as well as the use thereof, e.g., "The

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		General Guidelines for the Preparation of Abstracts of Patent Documents, using the checklist contained WIPO Standard ST.12 (Guidelines B-XI, 5 and Annex). o Once published, the abstract is not modified even if the content of the published patent differs in substance from that of the patent application (Guidelines C-II, 2). The abstract is not republished with the patent specification.	compounds are of the class of alkyl sulfonyl ureas, useful as oral anti-diabetics". Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, agents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.
			o The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words. The abstract should not exceed 15 lines of text. Abstracts exceeding 15 lines of text should be checked to see that it does not exceed 150 words in length since the space provided for the abstract on the computer tape by the printer is limited. If the abstract does not comply with the guidelines, the examiner should point out the defect to the applicant in the first Office action, or at the earliest point in the prosecution that the defect is noted,

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			and require compliance with the guidelines.
6. Requirements for Disclosure and Claims in Special Fields			
(1) Computer program deposits	Claim(s) This section deals with description requirements of claim(s), especially focusing on categories of inventions which require special judgment or treatment in examining patent applications relating to software-related inventions. (Examination Guidelines Part VII Chapter 1. Section 1.1) o Categories of Software-Related Inventions (1) Invention of a process When a software-related invention is expressed in a sequence of processes or operations connected in time series, namely procedure, the invention can be defined as an invention of	The EPC requires the description to be in writing, an exception being made for microorganisms under Rule 30 to 34. No such exception exists allowing the disclosure through a mere deposit of a computer program. In the particular case of inventions in the computer field, program listings in programming languages cannot be relied on as the sole disclosure of the invention. The description, as in other technical fields, should be written substantially in normal language, possibly accompanied by flow diagrams or other aids to understanding, so that the invention may be understood by a person skilled in the art who is deemed not	A "computer program", as the term is used in USPTO practice, is a plan or routine or set of instructions for solving a problem with a computer, controlling the management or internal operation of the computer, or having the computer direct the operation of an external device. It may take several conventional forms or embodiments, including: (a) electrical computer programs; (b) computer program listings: and (c) computer program flowcharts. The submission of "computer program listings" is governed by 37 CFR 1.96. See

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	a process (including an invention of a process of manufacturing a product) by specifying such a procedure. (2) Invention of a product When a software-related invention is expressed as a combination of multiple functions performed by the invention, the invention can be defined as an invention of a product by specifying such functions. A program or data can be defined in the following manners: (a) "A computer-readable storage medium having a program recorded thereon" can be defined as "an invention of a product." "A computer-readable storage medium having structured data recorded thereon" can also be defined as an invention of a product, where processing performed by a computer is specified by the data structure recorded thereon. (Examination Guidelines Part VII Chapter 1. Section 1.1.1)	to be a specialist in any specific programming language, but does have general programming skills. Short excerpts from programs written in commonly used programming languages can be accepted if they serve to illustrate an embodiment of the invention.For further details regarding computer related inventions see also the Report for Trilateral Project 12.5.	MPEP 608.05(a). A computer program listing, as used in the rule, means the printout that lists, in proper sequence, the instructions, routines, and other contents of a program for a computer. The listing may be either in machine or machine-dependent (object or source) programming language which will cause a computer to perform a desired task, such as solving a problem, regulating the flow of work in computer, or

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o In principle, program listings should not be included in the specification or drawings. However, if they are short excerpts written in a computer language generally known to a person skilled in the art and helpful for understanding the invention, such listings are allowed to be included. ("Program listings" can be submitted and filed as reference material. However, the specification cannot be amended on the basis of such reference material.) (Examination Guidelines Part VII Chapter 1. Section 1.2.2 (3))		controlling or monitoring events. The general description of the computer program listing will appear in the specification while the computer program listing may appear either directly or as a computer program listing on compact disc appendix to the specification and be incorporated into the specification by reference. The requirements for sufficient disclosure of inventions involving computer programming is the same as for all inventions sought to be patented. Namely, there must be an adequate written description, the original disclosure should be sufficiently enabling to permit one skilled in the art to make and use the invention as claimed, and there must be presentation of the best mode for carrying out the invention. Sufficiency of disclosure issues in computer cases necessarily will require an inquiry into both the sufficiency of the disclosed hardware as well as the disclosed software due to the interrelationship and interdependence of computer hardware

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			and software. The guidelines for determining sufficiency of disclosure are set forth in MPEP 2106.01. The manner of claiming inventions involving computer programs, like all other inventions, is governed by 35 U.S.C. 112, second paragraph. The claims must accurately define the invention and the specification must describe and identify the combinations of elements which perform the functions noted in the claims.
			A computer program listing contained on 300 printout lines or less may be submitted either as drawings (in compliance with 37 CFR 1.84), as part of the written specification (in compliance with 37 CFR 1.52), or on compact disc (in compliance with 37 CFR 1.52(e)). A computer program listing contained on 301 printout lines or more must be submitted as ASCII files on compact disc (in compliance with 37 CFR 1.96(c)). A computer program listing of more than 300 lines will not be printed in any patent application publication,

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			patent or Statutory Invention Registration. See 37 CFR 1.96(c).
(2) Chemistry	o In the case of an invention of a chemical compound, for in stance, the invention should be deemed as clearly explained if the chemical compound is expressed either by name or by chemical structural formula. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (2) ①) o In the technical field of chemical substances, etc., unless a person skilled in the art cannot understand how to make another product defined by its function or characteristic, etc. other than products of which manufacturing method is concretely described in the detailed description of the invention (or those which can be made from these products taking into consideration the common general knowledge), the description of the detailed description of the invention is violating the enablement requirement (For example, where a large amount of trials and errors or complicated	The requirements for disclosure and claims apply equally to all fields of technology and, with the exception of microorganism deposits, the EPC nowhere provides for any distinction in that respect depending on the technical field of the patent application. It is however true that some problems relating to claim drafting or disclosure requirements are specific to chemistry and might be worth mentioning in this study. In the following, the most relevant aspects are mentioned. (i) When the patent application is for new chemical compounds, is it necessary to state their use or effect in the description? This is not necessary purely for reasons of disclosure. It might however be necessary, in most cases, in order to establish an inventive step of the claimed compounds in comparison with prior art compounds.	USPTO chemical patent practice has raised issues not generally considered in regard to mechanical or electrical matters or at least not considered to the same degree or frequency. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B, and C." Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. Markush practice is employed for claiming a genus expressed as a group consisting of certain specified materials or steps (See Section 3. (3) (g)). Support for generic claims based on disclosure of species raises predictability and

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	experimentation are needed to find a way to carry out the invention beyond the reasonable extent that can be expected from a person skilled in the art.) (Examination Guidelines Part I Chapter 1. Section 3.2.1 (2) ②)		enablement questions relative to claim scope (see section 3 (4)). Questions of industrial applicability may be more difficult
	o In the case of the invention of a chemical compound, it is necessary to describe more than one specific use with technical significance in order to show that the chemical compound concerned can be used. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (2) ③) o In the case of inventions in technical fields of chemical substances, etc., normally one or more representative embodiments or working examples are necessary which enable a person skilled in the art to carry out the invention. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (5))	(ii) Amendments of the disclosure after the filing date. Is it allowable for an amendment of the description to include, for instance, an advantage of the invention in relation to the state of the art, a property, new examples or other technical information? No generally. Such amendments would contravene Article 123 (2) except if the applicant can show that they derive directly and unambiguously from the original disclosure (see 7. (1) below). However, new subject-matter submitted is included in the file and may be used as evidence to establish an inventive step. (iii) Definition by parameters	to decide in regard to chemical matters that encompass chemical intermediates, utility for products where the invention is in the process of their production, type of testing needed to establish utility for drugs and dosage amounts (See section 3. (3) (viii)). An article may be claimed by a process of making it provided it is definite. Where an applicant's product may be incapable of description by product claims as is frequently the case with chemical compositions an applicant is entitled to product-by-process claims that recite the novel process of manufacture (MPEP 2113).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		The invention may be defined either in the description or in the claims through the use of parameters. However, this is only permissible when the invention cannot be adequately defined in any other way (Guidelines C-III, 4.11). Only parameters usual in the art should be employed.	
	o If a claim is defined in an alternative way by Markush-type formula with only a mode for carrying out a part of the claimed alternatives being described in the detailed description of the invention, and if there is a concrete reason that the descriptions of the mode for carrying out the part of alternatives does not make the rest of the alternatives to be carried out by a person skilled in the art even taking into consideration the common general knowledge as of the filing, then, such descriptions of the particular mode should not be deemed sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art. (Examination Guidelines Part I Chapter 1. Section 3.2.1 (6) ③)	iv) Request for further evidence to justify a broad claim As a general rule, the examiner should require further evidence in support of a broad claim only when he has strong reasons to believe that the description provides inadequate support for that claim. Unless the examiner is absolutely certain of his position, such reasons should be supported by a specific document.	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o When matters disclosed in a detailed description of the invention cannot be extended or generalized to the scope of matters in a claimed invention even if taking into account common general knowledge as of the filing, the description of the claims is considered not to comply with the requirements of Article 36(6)(i) of the Patent Act. (Examination Guidelines Part I Chapter 1. Section 2.2.1.1 (3))		
(3) Micro-biotechnology	Claim In a claim, a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein and a monoclonal antibody should be described as indicated below.	Differences appear in this field of technology, mainly as a consequence of allowing deposit of micro-organisms as a substitute for the written description.	(a) General Considerations The disclosure and claiming requirements in the field of microbiotechnology are consistent with the requirements set forth in sections 1 through 3, above. However, due to the nature of this technology, specialized fact situations are encountered and these situations must be separately addressed.
	(1) Genes ① A gene may be described by specifying its nucleotide sequence.	o Rules 26 to 29 provide for general definitions and specify which biological/biotechnological material is	The disclosure of microbiological inventions may present unique problems both as to written description and enablement. The

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	② A structural gene may be described by specifying an amino acid sequence of the protein encoded by the said gene. ③ A structural gene may be described by a combination of the terms "substitution, deletion or addition" or "hybridize" with functions of the gene, and if necessary, origin or source of the gene in a generic form (provided that the claimed invention is clear and the enablement requirement is met). ④ A gene may be described by specifying functions, physiochemical; properties, origin or source of the said gene, a process for producing the said gene, etc. (provided that the claimed invention is clear and the enablement requirement is met). (2) Vectors A vector should be described by specifying a base sequence of its DNA, a cleavage map of DNA, molecular weight, number of base pairs, source of the vector, process for producing the vector, function or characteristics of the vector,	excluded from patentability. o Rule 30 (1) specifies the requirements for applications relating to nucleotide or amino acid sequences. If nucleotide or amino acid sequences are disclosed in the European patent application, the description shall contain a sequence listing conforming to the rules laid down by the President of the European Patent Office for the standardised representation of nucleotide and amino acid sequences. o Biological matter which is not available to the public and which cannot be described in the European patent application will be regarded as disclosed if the information relating to its deposit with a recognised depositary institution is provided in due time (Rule 31). o The relevant information under this provision concerns the classification of the biological material and significant differences from known biological material. For this purpose, the applicant must, to the	mere written words of a patent specification may not place the invention in the hands of the public upon the grant of a patent and, therefore, the quid pro quo of the patent grant is not achieved. Unlike a mechanical or chemical application, the ordinary skilled artisan, no matter how skillful, may not readily obtain the necessary starting materials to duplicate the microbiological invention using the written description of the invention alone. This is especially true when the microorganism is new and unavailable. A written description of the new microorganism and its isolation procedure may not place the microorganism in the hands of the practitioner due to repeatability considerations.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	etc. (3) Recombinant vectors A recombinant vector may be described by specifying at least one of the gene and the vector. (4) Transformants A transformant may be described by specifying at least one of ① its host and ② the gene which is introduced (or the recombinant vector) (provided that the claimed invention is clear and the enablement requirement is met). (5) Fused cells A fused cell may be described by specifying parent cells, function and characteristics of the fused cell, or a process for producing the fused cell, etc. (6) Recombinant proteins ① A recombinant protein may be described by specifying an amino acid sequence or a base	extent available to him, indicate morphological and biochemical characteristics and the proposed taxonomic description. If necessary, it has to be provided through experiments in accordance with the relevant standard literature. For characterising bacteria, for example, the relevant standard work would be R.E. Buchanan, N.E. Gibbons: Bergey's Manual of Determinative Bacteriology. Abbreviations for biological material or media are often less well known than the applicant assumes and should therefore be avoided or written in full at least once. o Against this background, information should then be given on every further specific morphological or physiological characteristic relevant for recognition and propagation of the biological material, e.g. suitable media (composition of ingredients), in particular where the latter are modified. o If biological material is deposited that	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	sequence of structural gene encoding the said amino acid sequence. ② A recombinant protein may be described by a combination of the terms "substitution, deletion or addition" and functions of the recombinant protein, and if necessary, origin or source of the recombinant protein in a generic form (provided that the claimed invention is clear and the enablement requirement is met). ③ A recombinant protein may be described by specifying functions, physiochemical, origin or source of the said recombinant protein, a process for producing the said recombinant protein, etc. (provided that the claimed invention is clear and the enablement requirement is met). (7) Monoclonal antibodies A claim directed a monoclonal antibody may be defined by specifying any of antigen recognized by it, hybridoma which produces it, or cross-reactivity, etc. (Examination Guidelines Part VII Chapter 2.	cannot replicate itself but must be replicated in a biological system (e.g. viruses, bacteriophages, plasmids, vectors or free DNA or RNA), the above-mentioned information is also required for such biological system. If, for example, other biological material is required, such as host cells or helper viruses, that cannot be sufficiently described or is not available to the public, this material must also be deposited and characterised accordingly. In addition, the process for producing the biological material within this biological system must be indicated (Guidelines C-II, 6.) o If biological material already deposited ceases to be available from the recognised depositary institution, an interruption in availability shall be deemed not to have occurred if a new deposit of that material is made with a recognised depositary institution (Rule 33). o Rules 32 and 33 specify under which	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	Section 1.1.1)	conditions deposited biological material referred to in a patent application shall be made available to a third person upon request, depending on whether the request is made before or after the date of publication of the European application	
	Detailed description of the invention (i) Genes, vectors or recombinant vectors A process for producing a gene, a vector or a recombinant vector should be described by respective origin or source, means for obtaining a vector to be used, an enzyme to be used, treatment conditions, steps for collecting and purifying it, or means for identification, etc. If genes are claimed in a generic form and a large amount of trials and errors or complicated experimentation are needed to produce those genes beyond the reasonable extent that can be expected from a person skilled in the art, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to make the product.		A deposit procedure exists to supplement the patent specification and tender it enabling in order to render the specification repeatable. See In re Argoudelis. Deposits of biological material are discussed in Section 6. (3) (b), infra.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	For example, in cases where a claimed invention includes the gene actually obtained and many of genes whose identity is extremely low to the said gene obtained and is specified by their function and that as a result, many of genes which do not have the same function as the said gene obtained are included in the genes whose identity is extremely low, a large amount of trials and errors or complicated experimentation are generally needed to select the genes with the same function as the said gene obtained among the genes whose identity is extremely low beyond the reasonable extent that can be expected from a person skilled in the art, and therefore, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to make the product		
	(ii) Transformants A process for producing a transformant should be described by a gene or a recombinant vector introduced, a host (a microorganism, a plant or an animal), a method of introducing gene or		(3)Disclosure in Detailed Explanation of Invention A. Microorganism used in an invention (a) Whichever classification unit is employed to express in the claim a microorganism used

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	the recombinant vector into the host, a method of selectively collecting the transformant, or means for identification, etc. (iii) Fused cells A process for producing a fused cell should be described by stating pretreatment of the parent cells, fusion condition, a method of selectively collecting the fused cell, or means for identification, etc.		in an invention, it is necessary that an example of the strain used in an invention (e.g., Aspergillus nigar FERM P-A) be set forth. When a microorganism used in an invention is not easily available to a person having ordinary skill in the art, a deposit number of said microorganism deposited must be described in the specification as filed. When a microorganism used in an invention is readily available to those having ordinary skill in the art, a source of supply of said microorganism (e.g., in the case of a commercially available microorganism, a supply source, a tradename or a registered trademark thereof and, in the case of a stored microorganism, a storage institution and a storage number of said strain) must be also described in the specification as filed. Furthermore, for all microorganisms disclosed in working examples, accession numbers or supply sources thereof must be described.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	(iv) Recombinant proteins A process for producing a recombinant protein should be described by stating means for obtaining a gene encoding the recombinant protein means for obtaining, an expression vector used, means for obtaining a host, a method for introducing the gene into the host, steps for collecting and purifying the recombinant protein from the transformant into which the gene has been introduced, or means for identification of the obtained recombinant protein, etc.		(b) In the case where a microorganism used in an invention is a strain, it is necessary to clearly describe characteristics of the strain and the differences (microbiological properties and effects) between said strain and known species of the same species. (c) When a microorganism used in an invention is a known species or a variant, it is necessary to indicate a literature that discloses said known species and to describe its scientific name and the reasons why the microorganism used in an invention is identified as the known species or variant.
	(v) Monoclonal antibodies A process for producing a monoclonal antibody should be described by stating means for obtaining or producing immunogen, a method for immunization, a process for selectively obtaining antibody producing cells, or means for identification of the monoclonal antibody, etc.		(d) When a microorganism used in an invention is a new species (including the case where it is expressed as a strain), it is necessary to fully describe the taxonomical properties of said microorganism and clarify the reasons why the microorganism is recognized as a new species, if necessary, with its microscopic photograph or electron microscopic photograph attached to the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			specification. That is, it is necessary to clearly describe the difference between said new species and the conventional analogous species and to also describe the name of literature on which the recognition of the microorganism as a new species has been based. Furthermore, the new species is desirably named in accordance with the Rules of International Nomenclature.
	(vi) Deposit of microorganisms, etc. (see "Deposit and Furnishing of Microorganisms") (a) For an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc. produced by the use of a microorganism, etc. ("a microorganism, etc." here includes a microorganism, a plant and an animal), a process for producing the said product should be described in the specification as filed so that a person skilled in the art can make it. Further, the microorganism used in the process should be deposited and its accession number should be described in the		3. Time of making an original deposit 37 CFR 1.804 specifies the time for making an original deposit. It is recommended that a deposit be made before the filing date of the application. However, for the purposes of complying with the requirements of 35 U.S.C. 112, a deposit of a biological material may be made at any time before filing the application for patent or during the pendency of the application subject to the conditions of 37 CFR 1.809. Where a deposit is needed to satisfy the requirements of 35 U.S.C. 112 and it is made during the pendency of the application, it must be made no later than the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	specification as filed unless the microorganisms readily available to a person skilled in the art. (b) For an invention of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, a monoclonal antibody, etc. when it is not possible to describe a process for producing the said product in the specification in such a manner that a person skilled in the art can make it, the obtained transformant (including a transformant which produces a recombinant protein) or the fused cell (including a hybridoma which produces a monoclonal antibody) into which the gene, the vector, the recombinant vector has been introduced, should be deposited and its accession number should be described in the specification as filed. (c) Generally, the acquisition of a hybridoma producing a monoclonal antibody which satisfies limitative conditions, (e.g., a monoclonal antibody whose affinity to the		time period set by the examiner at the time the Notice of Allowance and Fee(s) Due is mailed. See MPEP 2406. When the original deposit is made after the effective filing date of an application for patent, an applicant is required to promptly submit a statement from a person in a position to corroborate that the biological material specifically identified in the application (the filing date of which is relied upon) as filed. See MPEP 2406.02.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	antigen A is specified by the limitative coupling constant,) is not reproducible. Therefore, in case that the claimed invention is related to a monoclonal antibody which satisfies limitative conditions or a hybridoma producing the said monoclonal antibody, the said hybridoma should be deposited and its accession number should be described in the specification as filed, except where the hybridoma can be created by a person skilled in the art on the basis of the description in the specification. (Examination Guidelines Part VII Chapter 2. Section 1.1.2)		
	Deposit and Furnishing of Microorganisms When describing inventions involving a microorganism itself or a use for a novel microorganism, and when it is impossible to describe how to originate the microorganism so that the person skilled in the art can produce the microorganism, the microorganism must be deposited according to Article 27-2 of		4. Duration of the deposit The term of deposit must satisfy the requirements of the Budapest Treaty which sets a term of at least 30 years from the date of deposit and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In the event that the 30-year term covers the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	Regulations under the Patent Act. Article 27-2 of Regulations under the Patent Act (Deposition of microorganisms) 1 A person desiring to file a patent application for an invention involving or using a microorganism shall attach to the request a copy of the latest receipt referred to in Rule 7 of the Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (hereinafter referred to as "Treaty") for the deposit of the microorganism issued by the International Depositary Authority defined in Article 2(viii) of the Treaty, or a document certifying the fact that the microorganism has been deposited with an institution designated by the Commissioner of the Patent Office, except where the microorganism is readily available to a person skilled in the art to which the invention pertains. 2 Where an accession number is newly given after the filing of a patent application to the		17-year term or 20-year term of the patent plus 6 years to include the Statute of Limitations, no further requirement is necessary. 5. Reference to the deposit in patent The specification must contain (a) the accession number for the deposit, (b) the date of the deposit, (c) a description of the deposited biological material sufficient to specifically identify it and to permit examination, and (d) the name and address of the depository. See 37 CFR 1.809(d). If the criteria in Lundak are met, the address of the depository as well as the deposit number may be inserted without new matter problems arising. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement. See MPEP 2411.05.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	deposit of a microorganism under the preceding paragraph, the applicant for a patent or the patentee shall notify the Commissioner of the Patent Office without delay. 3 The notification under the preceding paragraph shall be made in accordance with Form 32 with respect to a patent application, or Form 33 with respect to an International Patent Application.		
	Article 27-3 of Regulations under the Patent Act (Furnishing of microbiological samples) 1 A person who intends to work for the purpose of tests or experiments an invention involving or using a microorganism deposited in accordance with the preceding Article may be furnished with a sample of the microorganism provided that: (i) registration for the establishment of a patent right to the invention involving or using the microorganism has been made; (ii) the person received a warning given in the		6. Public Availability Upon grant of a U.S. patent, all restrictions on the deposit are to be irrevocably removed. 37 CFR 1.808(a)(2). See MPEP 2410 and 2410.01. 7. Guidelines for deposits The deposit rules (37 CFR 1.801 to 1.809) went into effect on January 1, 1990. The deposit rules set forth examining procedures and conditions of deposit which must be satisfied in the event a deposit is required. The rules do not address the substantive issue

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	form of a document describing the contents of the invention involving or using the microorganism in accordance with Article 65(1) of the Patent Act; or (iii) such is necessary in order to prepare a written argument referred to in Article 50 of the Patent Act (including its application under Article 159(2) (including its application under Article 174(2)) and Article 163(2)). 2 A person who has been furnished with a sample of the microorganism in accordance with the preceding paragraph shall not permit a third party to utilize the sample of the microorganism. (Examination Guidelines Part VII Chapter 2. Section 5.1)		of whether a deposit is required under any particular set of facts. The deposit rules are effective for all applications filed on or after January 1, 1990, and for all reexamination proceedings in which the request for reexamination was filed on or after January 1, 1990. See MPEP 2402 to 2411.05.
			8. Need for deposit 37 CFR 1.802(a) permits a deposit of a biological material to be referenced in a patent application where an invention is, or relies on, a biological material. The invention may rely on a biological material for the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			purposes of making or using the invention, either as a preferred mode or an alternative mode of operation. A reference to a deposit may be included in a specification even though the deposit is not required to satisfy the requirements of 35 U.S.C. 112. 9.Deposit of other subject matter Current USPTO policy has been to limit deposits to the subject matter specified in (b)2 above. 10. Replacement of Deposits 37 CFR 1.805 governs the deposit of a biological material to replace or supplement a previous deposit. The term "replacement" is directed to those situations where one deposit is being substituted for another. An applicant may have greater latitude in replacing a deposit during the pendency of an application than after the patent is granted.

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			Replacement will typically take place where the earlier deposit is no longer viable. The term "supplement" is directed to those situations where the earlier deposit is still viable in the sense that it is alive and capable of replication either directly or indirectly, but has lost a quality (e.g., purity, functionality) it allegedly possessed at the time the application is filed. See MPEP 2407.
7. Others (1) New matter/amendment	o An amendment including anything outside the scope of "matters described in a description, etc. as filed" (e.g., an amendment containing new matter) is not acceptable. o The phrase, "matters described in a description, etc. as filed" means not only "matter expressly present in a description, etc. as filed" but also "matter inherently present in a description, etc. as filed." o In order to conclude that an amendment is done within the scope of "matters inherently present in the description, etc. as filed," the	o The applicant is allowed at least one opportunity of amending the description, claims and drawings of his own volition (Article 123 (1)). o A patent application or a patent (in opposition proceedings) may, however, not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123 (2)). o During opposition proceedings amendment in such a way as to extend the protection conferred is not allowed (Article 123 (3)). Where the protection conferred by the	o 35 U.S.C. 132 prohibits the introduction of new matter by way of amendment into the disclosure of the invention. Matter not in the original specification, claims or drawings is usually new matter. When new matter is introduced into the specification, the amendment should be objected to under 35 U.S.C. 132 and a requirement made to cancel the new matter-clearly identified by the examiner. If the new matter has been entered into the claims or affects the scope of the claims, the claims affected should be rejected under 35 U.S.C. 112, first paragraph, because the new matter is not described in

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	meaning of the particulars of the amendment shall be evident to a person skilled in the art in light of common general knowledge as of the filing, as if it were written in the description, etc. as filed, even though it is not expressly present in the description, etc. as filed. o Addition of well-known art or commonly used art is not acceptable by simply arguing “as they are.” This addition is acceptable only if such art is inherently present in a description, etc. as filed, that is, the art is logically acknowledged by a person skilled in the art as if it were written in a description, etc. as filed. o In some cases, a certain matter is considered inherently present to a person skilled in the art with help of other plural written matters in a description, etc. as filed (For example, embodiments and problems to be solved of an invention, a description and drawings). (Examination Guidelines Part Ⅲ Chapter 1. Section 3.)	European patent has been extended, this is a ground for revocation (Article 138 (1) (d)). However, limiting the scope of a claim by using a "disclaimer" to exclude a technical feature not disclosed in the application as filed does not infringe Art. 123(2) if the disclaimer aims at (Guidelines C-IV, 5.3.11): (i) restoring novelty over a disclosure under Art. 54(3); (ii) restoring novelty over an accidental anticipation (*) under Art. 54(2) (iii) removing subject-matter which, under Art. 52 to Art. 57, is excluded from patentability for non-technical reasons. For example, the insertion of "non-human" in order to satisfy the requirements of Art. 53(a) is allowable. (*) 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. An accidental disclosure has nothing to do with the	the application as originally filed.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		teaching of the claimed invention, since it is not relevant for examining inventive step. For example, this is the case when the same compounds serve as starting materials in entirely different reactions yielding different end products. A prior art, the teaching of which leads away from the invention, however, does not constitute an accidental anticipation; the fact that the novelty destroying disclosure is a comparative example is also insufficient for achieving the status of "accidental". However, an undisclosed disclaimer is not allowable if: (i) it is made in order to exclude non-working embodiments or remedy insufficient disclosure; (ii) it makes a technical contribution. An undisclosed disclaimer is, in particular, not allowable in the following situations: (i) the limitation is relevant for assessing inventive step; (ii) the disclaimer, which would otherwise be	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		allowable on the basis of a conflicting application alone (Art. 54(3)), renders the invention novel or inventive over a separate prior art document under Art. 54(2), which is a not accidental anticipation of the claimed invention; (iii) the disclaimer based on a conflicting application removes also a deficiency under Art. 83; A disclaimer should remove no more than is necessary either to restore novelty or to disclaim subject-matter excluded from patentability for non-technical reasons. A claim containing a disclaimer must meet the clarity and conciseness requirements of Art. 84. In the interest of the patent's transparency, the excluded prior art should be indicated in the description in accordance with Rule 42(1)(b) and the relation between the prior art and the disclaimer should be shown	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o It is prohibited to make an amendment whereby inventions, of which patentability has been determined in a notice of reasons for refusal, among claimed inventions prior to the amendment, and inventions amended after the notice of reasons for refusal is given do not meet the requirements for unity of invention because they do not have any same or corresponding special technical feature. (Examination Guidelines Part Ⅲ Chapter 2. Section 3.) o The amendment of the scope of claims after the final notice of reasons for refusal shall be limited to those for the following purposes; (i) the deletion of a claim or claims as provided in Article 36(5); (ii) restriction of the scope of claims (limited to the cases where the restriction is to restrict matters required to identify the invention stated in a claim or claims under Article 36(5), and the industrial applicability and the problem to be solved of the invention stated in	o Unless having been invited to do so in order to meet formal requirements, the applicant is not allowed to amend the description, the claims or the drawings before receiving the search report (Rule 137(1)). However, the applicant may amend the application, of his own volition, after receiving the search report and before receipt of the first communication from the Examining Division. After receipt of the latter, the applicant may amend once the description, the claims and any drawing, provided this is done at the same time as the reply to the communication. No further amendment may be made without the consent of the Examining Division, which means that amendments are still allowed at this stage especially if they are in response to objections raised and necessary to overcome the latter or if they are not too extensive (Guidelines C-VI, 4.7 and 4.8).	Amendments need not be construed as containing new material if it contains mere embellishment of technical improvement of feature disclosed in original application that does not contribute to its novelty, utility, or non-obviousness. New matter is not introduced by amendments that merely clarify or make definite that which was expressly or inherently disclosed in the application as originally filed, or that conform to matter originally disclosed in drawings or claims. See Litton Sys., Inc. v. Whirlpool Corp., 221 USPQ 97 (Fed. Cir. 1984). A new matter amendment of the drawings is ordinarily not entered.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	the said claim or claims prior to the amendment are identical with those after the amendment); (iii) the correction of errors; and (iv) the clarification of an ambiguous statement (limited to the matters stated in the reasons for refusal in the notice of reasons for refusal). (Article 17-2 (5) of the Patent Act)		
		o No substantive amendment is acceptable, once the applicant has given his consent to the text proposed for grant by the Examining Division, unless the latter becomes aware of facts or documents causing it of its own volition to resume the proceedings because of those circumstances such as to render non-patentable some subject-matter claimed (Guidelines C-VI, 4.10). Reopening examination is no longer possible when the decision to grant the patent has been dispatched.	o For applications filed on or after September 21, 2004, a preliminary amendment that is present on the filing date of the application is part of the original disclosure of the application. For applications filed before September 21, 2004, a preliminary amendment that is present on the filing date of the application is part of the original disclosure of the application if the preliminary amendment was referred to in the first executed oath or declaration under 37 CFR 1.63 filed in the application. See MPEP 714.01(e), 602 and 608.04(b).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			o Where the new matter is confined to amendments to the specification, review of the examiner's requirement for cancellation is by way of petition. But where the alleged new matter is introduced into or affects the claims, thus necessitating a rejection under 35 U.S.C. 112, first paragraph, the question becomes an appealable one, and should not be considered on petition even though that new matter has been introduced into the specification also. See MPEP 608.04(c).
(2) Specification amendments vs. file wrapper documents	o When written opinion or amendment is submitted in response to the first notice of reasons for refusal, the examiner should examine as follows; (1) Examination of the content of a written opinion, amendment etc. The examiner should examine the content of a written opinion, amendment, etc. and judge whether the previous reasons for refusal was resolved or not. In particular, where only a written opinion was submitted without amendment in response to	o Amendments to the description are never allowed when they introduce subject-matter which extends beyond the content of the application as field (Article 123 (2)). o Further information regarding relevant prior art is, however, not normally objected to (Guidelines C-VI, 5.3) and may be necessary to comply with Rule 42(1)(b); see (4) below. o The amendment may also be permitted if, in the context of the invention, a particular feature would appear so well known to the	o An amendment that is received in the USPTO on or before the mail date of the first Office action is called preliminary amendment (see 37 CFR 1.115). Amendments submitted in response to a non-final Office action is governed by 37 CFR 1.111. Amendment submitted after final rejection is governed by 37 CFR 1.116 and will not be entered unless approved for entry by the examiner.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	the notice of refusal, the examiner should consider sufficiently the content of the written opinion and examine whether the reasons for refusal indicated in the notice of reasons for refusal can be resolved or not. (2) Handling of amendment Where an amendment was submitted in response to the first notice of reasons for refusal, the examiner should accept and examine it based on the description, scope of claims, drawings etc. as amended. (3) Handling of written opinions, reports of experiment results, etc. Written opinions and reports of experiment results submitted in response to the notice of reasons for refusal can not substitute for the detailed description of the invention in the description, but if the applicant argued and proved thereby that the matters disclosed in the description or drawings originally attached to the request are correct and proper, the examiner should take into consideration of these particulars.	person skilled in the art that its introduction could be regarded as an obvious clarification (Guidelines C-VI 5.3.3).	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	(Examination Guidelines Part IX Chapter 2. Section 4.3.2)		
	o Based on the provision in Article 194 (1) of the Patent Act, the examiner can request the applicant for submission of documents and other articles required for the examination. (Examination Guidelines Part IX Chapter 2. Section 5.)	o Amendment by the introduction of further examples or further statements of advantage is not allowed (Guidelines C-VI, 5.3.4). Such information can, however, be taken into consideration by the examiner when assessing inventive step or whether the invention can be applied over the whole field claimed (Guidelines C-VI, 5.3.5). Information of this kind is added to the part of the file which is open to public inspection, its presence in the file being mentioned on the cover page of the printed patent specification (Guidelines C-VI, 5.3.6).	Amendments to the specification, claims and drawings that have been entered become a permanent part of the record and are considered to be part of the disclosure of the application to be published upon allowance of the application. When the Office publishes the patent application under 35 U.S.C. 122(b), the Office may include preliminary amendments in the patent application publication. See MPEP 714.01(e) and 1121.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			o All other papers submitted by the applicant during the prosecution of the application are considered to be file wrapper documents. These documents include for example, affidavits or declarations filed under 37 CFR 1.131, affidavits or declarations filed under 37 CFR 1.132, exhibits accompanying the affidavit or declaration and any remarks accompanying the amendments to the specification, claims and drawings.
			o File wrapper documents become a permanent part of the record and are available to the public when the application is published/issued. However, these documents are not considered to be part of the disclosure of application and will not be published in the patent application publication or the printed patent upon allowance of the application.
(3) Oaths/declarations to overcome rejections	o The Japanese Patent Act does not provide a legal basis on oaths or declarations.	o Sworn statements in writing are admitted as means of giving evidence (Article 117 (1) (g)) and can be used to rebut allegations (Guidelines C-VI, 13.3). They can however, be dispensed with, as facts adduced by a	o Applicant may file an affidavit or declaration under 37 CFR 1.131 to antedate a reference or activity that qualifies as prior art under 35 U.S.C. 102(a) or a reference that qualifies as prior art under 35 U.S.C. 102(e)

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		party will normally be deemed true if it is clear that no doubts exist concerning them or if facts do not contradict one another (Guidelines E-IV, 1.2). Therefore such statements are seldom used in pre-grant proceedings. More often they are submitted in opposition proceedings in order to prove allegations contested by the other party.	by establishing invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. See MPEP 715. Applicant may file an affidavit or declaration under 37 CFR 1.132 to traverse grounds of rejection and objection. See MPEP 716+. When any claim of an application is rejected under 35 U.S.C. 103(a) on a U.S. patent or U.S. patent application publication which is not prior art under 35 U.S.C. 102(b), and the invention defined by the claims in the application and by the claims in the patent or published application are not identical but are not patentably distinct, and the inventions are owned by the same party, the applicant may file an affidavit or declaration under 37 CFR 1.130 to disqualify the patent or published application as prior art. See MPEP 718. o All affidavits or declarations must be timely presented to be admitted. All admitted affidavits or declarations will be considered

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			and commented upon by the examiner in the next office action. Affidavits or declarations should be scrutinized closely by the examiner and the facts presented weighed with care. The question of sufficiency of affidavits or declarations should be reviewed and decided by a primary examiner.
			o Affidavits or declarations are considered to be file wrapper documents and do become part of the permanent record when the application is issued. However, these documents are not considered to be part of the disclosure of the application and will not be published in the patent application publication or the printed patent upon allowance of the application.
(4) Disclosure requirements for prior art documents	o The detailed description of the invention shall provide the source of the information concerning the invention(s) known to the public through publication such as the name of the publication and others where the person requesting the grant of a patent has knowledge of any invention(s) related to the said	o The description should mention any background art of which the applicant is aware and which can be regarded as useful for understanding the invention and its relationship to the prior art (Rule 42(1)(b) 27 (1) (c)). o Identification of documents reflecting such	o In order to overcome the prior art rejections, applicant may attack the operability, utility and enablement of the prior art documents by way of affidavits or declarations filed under 37 CFR 1.132. The affidavits or declarations must set forth facts, not merely conclusions and the facts presented must be pertinent to

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	invention, that has been known to the public through publication at the time of filing of the patent application. (Article 36(4)(ii) of the Patent Act)	art, especially patent documents, should preferably be included. Insertion into the statement of prior art of references to documents identified subsequently, for example in the search report, is required, where necessary, to put the invention into its proper perspective (Guidelines C-II, 4.3).	the rejection, otherwise, the affidavits or declarations have no probative value. See MPEP 716.07.
	o When there is no information on prior art documents to be described at the beginning of the filing, it is desirable to describe the effect with reasons in the detailed description of the invention. For example, when the prior art that an applicant knows is not the one relating to the invention described in a publication, the effect should be described. (Examination Guidelines Part Ⅰ Chapter 3. Section 3.2 (3))	o Lists of several reference documents relating to the same feature or aspect of the prior art are not required; only the most appropriate one should be referred to. The examiner, however, does not require the excision of such unnecessary matter, except when it is very extensive (Guidelines C-II, 4.4). o The prior art should not be referred to in a manner likely to mislead. The impression should not be given that the prior art had solved less of the problem than was actually the case (Guidelines C-II, 4.5).	o Every patent is presumed valid (35 U.S.C. 282) and that presumption includes the presumption of novelty, nonobviousness and utility. A prior art reference must be enabling in order to anticipate applicant's invention. Affidavits or declarations attacking the enablement of the prior art documents will be reviewed and considered by the primary examiner.
(5) Disclosure requirements for priority documents	o For saying that the claimed invention of the application claiming priority in Japan is disclosed by the whole application documents	o If the priority of an earlier application is claimed, the request for grant must contain a declaration to this effect (Rule 41(2)(g)). It is	o An applicant's foreign application must contain a disclosure of the invention adequate to satisfy the requirements of 35 U.S.C. 112,

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	of the first application, the claimed invention of the application in Japan understood by consideration of the whole description of the application documents of the application in Japan shall be within the scope of the matters disclosed in the whole filing documents of the first application. o It shall be determined whether the claimed invention of the application in Japan is within the scope of the matters disclosed in the whole filing documents of the first application or not, depending on the examples of new matters. (Examination Guidelines Part IV Chapter 1. Section 4.1)	not required, however, to refer to priority in the description. o A European patent application may claim rights of priority based on more than one earlier application (Article 88(2) and (3)). It is, however, not permitted to mosaic priority documents. An exception may arise where one priority document refers to the other (Guidelines C-V, 1.5). o If certain elements of the invention for which priority is claimed do not appear among the claims formulated in the previous application, they are nonetheless covered by the right of priority, provided that the documents of the priority application as a whole disclose such elements (Article 88 (4) and Guidelines C-V, 2.2 to 2.4). The basic test to determine whether a claim is entitled to priority is the same as the test	first paragraph if the later filed U.S. application claiming that invention is to be accorded benefit of the filing date of the foreign application under 35 U.S.C 119(a). The disclosure of the invention in the foreign application must be sufficient to enable any person skilled in the art to make and use the invention and must disclose the best mode. See Kawai et al v. Metlesics et al, and Taylor v.Brackman, supra, and Section 2. (3) (vi) (c). It is the responsibility of the examiner to determine whether disclosure in the foreign application complies with the requirements of 35 U.S.C. 112, first paragraph and to determine whether applicant is entitled to the right of priority.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		of whether an amendment to an application satisfies the requirement of Article 123 (2) ("Novelty test", Guidelines C-V, 2.2).	
(6) Disclosure requirements for internal priority documents	o It cannot be said that the claimed invention of the later application claiming priority is disclosed in the description etc. originally attached to the request of the earlier application unless the claimed invention of the later application, which is understood by considering what is disclosed in the description etc. of the later application, is within the scope of matters disclosed in the description etc. originally attached to the request of the earlier application. o It is determined whether the claimed invention of the later application is within the scope of matters disclosed in the description etc. originally attached to the request of the earlier application or not, depending on the examples of new matters.	o There are no specific provisions with respect to internal priority in the EPC. Article 87 EPC applies equally to earlier European and international applications (Guidelines C-V, 1.3). Formal and substantive requirements are therefore the same as for other priority documents, i.e. national filings. o The EPC does not contain any provision according to which a European patent application is deemed to be abandoned as soon as it is used to claim priority for a new European patent application, designating at least one identical Contracting State. The applicant is, however, not allowed to claim in both applications the same invention (Guidelines C-IV, 7.4).	o One of the provisions of the Uruguay Round Agreements Act (URAA - effective date of June 8, 1995) is the establishment of a domestic priority system. The Act provides a mechanism to enable domestic applicants to quickly and inexpensively file provisional applications. See 35 U.S.C. 119(e). The filing date of a provisional application is the date on which a specification complying with 35 U.S.C. 112, first paragraph and any drawings required by 35 U.S.C. 113 are filed. No claims are required and no oath or declaration is required. A provisional application is not examined and will automatically be abandoned 12 months from its filing date and will not be subject to revival thereafter. A provisional application is a regular national filing that starts the

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	(Examination Guidelines Part IV Chapter 2. Section 4.1)		
			Paris Convention priority year. A nonprovisional application may be filed within 12 months from the filing date of the provisional application claiming the benefit of the filing date of the provisional application under 35 U.S.C. 119(e). The written description and drawings (if any) of the provisional application must adequately support and enable the subject matter of the claim in the later-filed nonprovisional application. If a claim in the nonprovisional application is not adequately supported by the written description and drawings (if any) of the provisional application, that claim in the nonprovisional application is NOT entitled to the benefit of the filing date of the provisional application. See MPEP 201.11, subsection I.A.
(7) Determination of invention based on disclosure - Does applicant or the examiner	o The scope of claims shall state a claim or claims and state for each claim all matters	o An independent claim should specify clearly all of the essential features needed to	o According to USPTO practice, the invention at issue in a given patent application is that

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
make the determination?	necessary to specify the invention for which the applicant requests the grant of a patent. In such case, an invention specified by a statement in one claim may be the same invention specified by a statement in another claim. (Article 36 (5) of the Patent Act) o Since it is the applicant who determines for what invention to seek a patent, this Article sets forth that the applicant shall state in the claim all matters the applicant himself/herself deems necessary to define the invention for which a patent is sought. (Examination Guidelines Part I Chapter 1. Section 2.1 (1))	define the invention (Guidelines C-III, 3.4). o In addition, claims must be supported by the description (Article 84). There must be a basis in the description for the subject-matter of every claim and the scope of the claims must not be broader than is justified by the extent of the description and drawings (Guideline C-III, 6). o Any inconsistency between the description and the claims should be avoided (Guidelines C-III, 4.3). For example, if the description leads the reader to believe that a feature, not contained in an independent claim, is essential to the performance of the invention, then this feature must be brought into that claim or shown not to be essential.	defined by the scope of the claims. The scope of this invention is not necessarily measured by the scope of the disclosure. Thus, the claimed invention may be broader or narrower than a specifically disclosed embodiment. o By virtue of the fact that it is the applicant who presents claims to be examined, it can be said that it is the applicant who, at the least, begins the process of determining the invention for the purposes of patent protection. This process, begun by the applicant, is continued throughout the pendency of an application and is completed upon the grant of a patent. During the pendency of an application, the process of determining the scope of an invention is an objective one.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
	o Even though there is inconsistency between an invention found in a claim and an invention described in the specification and the drawings, the finding and examination of an invention should not be made solely on the basis of the description in the specification and the drawings, disregarding the statements of the claim. (Examination Guidelines Part II Chapter 2.(Novelty and Inventive Step) Section 1.5.1 (4))	o The drafting of the application is the applicant's responsibility (Guidelines C-II, 4.10). Thus the applicant makes the determination of the invention. However, if the claims are not consistent with the presentation made by the applicant in the description, the examiner has to raise an objection under Article 84. The Guidelines (C-III, 3.2) provide that the examiner should not allow unnecessary proliferation of claims but should not adopt an over-academic or rigid approach to the presence of a number of claims which are differently worded but apparently of similar effect. Special cases where two or more independent claims of, the same category are appropriate are dealt with in the Guidelines C-III 3.3. o In addition, if documents have been found which are so relevant as to render the presentation of the invention no longer appropriate the examiner may indicate to the applicant that the problem to be solved is not correctly defined and require him	The initially presented claims are measured against the pertinent prior art and the scope of the enabling disclosure. The claims must also satisfy the definiteness requirements of 35 U.S.C. 112, second paragraph, as discussed in Section 3, above. o While the USPTO examiner may apply prior art in rejecting claims for lack of novelty or inventive step or may reject claims because they are broader than the enabling disclosure, often leading to a narrowing of the scope of the claims, it must be noted that these rejections may be successfully rebutted by the applicant without narrowing th claims. It is never the function of the examiner to determine what the invention is for the purposes of patent protection by reference to the examiner's perception of the invention from his/her reading of the disclosure. That is, the USPTO examiner may not conclude, from a review of the disclosure, that certain features of an invention are "indispensable" or

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		to amend the description and the claims accordingly (Rule 71(1), Guidelines C-VI, 3.7). o Thus the applicant makes the determination of the invention, but the examiner may influence, by his objections, this determination. o It is the applicant who presents the Claims to be examined. The examiner decides whether or not the Claims as suggested satisfy the various conditions of patentability. In so doing, the examiner may suggest amended claims in order to overcome the objection made. o The EPO examiner determines whether all essential features are in the independent claim.	"essential" and then require that these features be added to the claims.

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o On this point the EPO offers the following as clarification. o The term "essential feature(s)" does not mean "all those features described" nor does it necessarily mean the specific example of a particular feature. The features of any Claim may be set out as broadly as is justifiable from the disclosure without bringing it into conflict with the prior art. Nevertheless. all the essential features need to be present in an independent Claim (Guidelines C-III, 4.3 (ii) and 4.4)	
		o The EPO examiner must take the description into account in a reading of the Claims if only to assess support of the latter by the former. In so doing, he or she may be lead to the conclusion that the claimed apparatus or method would not work or achieve the objective of the application because a component of the apparatus or step in the method is not set out in the independent Claim or Claims. The may raise an objection that such a Claim lacks an	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		essential feature. It should be emphasised here that applicants can (and do) argue that an examiner is mistaken in his or her view that a certain feature is essential.	
		However, the EPC is interpreted as allowing a final rejection if examiner and applicant maintain opposed views in this respect. The ground of final rejection would be lack of the clarity in the Claims resulting from an apparent inconsistency between Claims and description, or lack of support in the description if the result expected from the working of the invention as claimed is not achieved. o In trying to remove the inconsistency between an independent Claims which lacks an essential feature and the description which shows the necessity of the feature, an applicant may propose deleting the feature from the description. This is regarded as an impermissible extension of the content of the application beyond that originally filed and maybe objected to under Article 123 (2).	

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
		o Similarly, an applicant may delete an apparently essential feature from a Claim in the course of examination. Although Claim broadening by omission of a feature is permissible when there is a basis for this in the original application, such broadening is not allowable when the feature is held to be essential for the performance of the invention. Under these circumstances, objection is raised under Article 123 (2).	
(8)Prohibited matters or inadmissible elements (e.g. superfluous elements, reference to the spirit or essence of the invention, violation of public order, morality or public health, trademarks)			

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
- Superfluous elements	o If there are expressions where optionally added items or selective items are described along with such words as “when desired,” “if necessary,” etc., or expressions including such words as “especially,” “for example,” “etc.,” “desirably,” and “suitably.”, there are some cases where the description of the claims is not clear. o Such expressions would leave unclear the condition on which of the optionally added or selective items are chosen, thus allow the claim statements to be interpreted in many ways. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (5) ④)	o Superfluous elements are prohibited in the European patent application (Rule 48(1)(c), Guidelines C-II, 7.4). Matter may become superfluous in the course of the examination (e.g. limitation of the claims to one of originally several alternatives).	
- Reference to the spirit or essence of the invention	o No comment	o General statements in the description which imply that the extent of protection may be expanded in some vague and not precisely defined way are objected to under Article 84 as this obviously obscures the scope of the claims (Guidelines C-III, 4.4).	o It is well known that an applicant is not required to comprehend the underlying scientific principle or theory upon which his/her invention rests and, therefore, need not include the same in an application.

COMPARATIVE STUDY OF PATENT PRACTICES ON REQUIREMENTS FOR DISCLOSURE AND CLAIMS

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
- Violation of public order, morality or public health	o Article 32 of the Patent Act provides that inventions liable to contravene public order, morality or public health shall not be patented. o The matters of the specification and the contents of the drawings attached to the request whose publication in the Patent Gazette is, in the view of the Commissioner of the Patent Office, liable to contravene public order or morality are not published in the Patent Gazette. (Article 32, Article 64 (2) of the Patent Act)	o Such matter is prohibited under Rule 48(1)(a). The kind of matter coming within this category are: incitement to riots or to acts of disorder; incitement to criminal acts; racial, religious or similar discriminatory propaganda; and grossly obscene matter (Guidelines C-II, 7.2). Such matter must be deleted before the publication of the application (Rule 48(2)).	o A rejection under 35 U.S.C. 101 for lack of utility should NOT be based on grounds that the invention is frivolous, fraudulent or against public policy. See Juicy Whip Inc. v. Orange Bang Inc., 51 USPQ2d 1700 (Fed. Cir. 1999) ("[Y]ears ago courts invalidated patents on gambling devices on the ground that they were immoral..., but that is no longer the law...Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted...we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public."). See MPEP 706.03(a).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
- Trademarks	o Where a claim includes a statement to define a product by means of a trademark, such a statement is deemed as making the claimed invention unclear unless it is clear to a person skilled in the art that the product had been maintained a certain quality, composition and structure, etc., at least for a certain period of time as of the filing. (Examination Guidelines Part I Chapter 1. Section 2.2.2.1 (3))	o If the examiner suspects that a word used in the description is a registered trade-mark, at least in certain Contracting States, he asks the applicant either to acknowledge the word as such or to state that, so far as he is aware, the word is not a registered trade-mark (Guidelines C-II, 4.18). In the claims, use of trade-marks is not allowed unless their use is unavoidable; they may be allowed exceptionally if they are generally recognised as having a precise meaning (C-III, 4.8).	o The use of trademarks and names used in trade in permitted in patent applications provided certain conditions are satisfied. Trademarks should always be capitalized and accompanied by generic terminology. Names used in trade are permissible in applications if their meanings are established by an accompanying definition or their meanings are well known and satisfactorily defined in the literature in the U.S. See MPEP 608.01 (v) and Section 2. (3) (iv) (c) above.
- Others		o Whereas fair comments e.g. in relation to obvious or generally recognised disadvantages, or disadvantages stated to have been found and substantiated by the applicant are allowed, libellous or similarly disparaging statements are not (Rule 48(1)(b), Guidelines C-II, 7.37.2.	o Derogatory remarks concerning the inventions of others, whether they are remarks concerning the products or processes of another or statements regarding the merit or validity of the applications or the patents of another, are prohibited. See MPEP 608.01 (r).

ITEM and SUBITEM	JAPAN PATENT OFFICE	EUROPEAN PATENT OFFICE	U.S. PATENT & TRADEMARK OFFICE
			o U.S. patents are not granted for any invention or discovery which is useful solely in the utilization of atomic energy. See MPEP 706.03 (b). All applications are also screened for subject matter, the disclosure of which might detrimentally impact the national security. If disclosure is determined to be detrimental to the national security, the Commissioner is notified and a Secrecy Order is issued to withhold the grant of a patent for such period as the national interest requires. See MPEP 115.

COMPARATIVE ANALYSIS

1. Legal Bases Concerning the Requirements for Disclosure and Claims

(1) Relevant provisions in laws and implementing regulations

The lists of the relevant provisions in laws and implementing regulations are shown in the Comparison Outline.

New provisions of the European Patent Convention ("EPC 2000")
(as published in the EPO Official Journal (2007), Special edition 1).
NB. The new European Patent Convention will enter into force on December 13, 2007).

The amendments brought to Articles 78, 83, 84 and 85 are not substantive in nature.

Article 80 has been brought in line with the standards laid down in Art 5 PLT 2000. The EPO provisions on the accordance of a filing date have been consolidated in the Implementing Regulations (Rule 40).

The new version of Article 123(3) extends to the whole patent (i.e., the claims, the description and the drawings, if any) the requirement that a European patent may not be amended in such a way as to extend the protection it confers. This principle is also applicable in all proceedings before the European Patent Office, as well as in national proceedings.

The Implementing Regulations to the EPC 2000 have been renumbered in order to allow insertion of new rules as well as transfer of elements to other provisions. The rules governing the application are now Rules 40 (date of filing), 42 (description), 43 (claims), 46 (drawings), 47 (abstract), 48 (prohibited matter) and 49 (presentation of the application),

The provisions relating to amendments and corrections are now Rule 137 (amendment) and 139 (corrections).

The provisions relating to special fields are now Rules 26 to 29 (biotechnological inventions, all aspects), Rule 30 (requirements relating to sequences), and Rules 31 to 34 (deposit of micro-biological material).

(2) Examination guidelines, manuals, standards, etc.

The items of the examination guidelines, manuals, standards, etc. relevant to the

requirements for disclosure and claims in each of three Offices are shown in the Comparison Outline.

(3) Background and purpose of the statutory requirements for disclosure

Three Offices agree that "patent right" is an exclusive right granted in return for the disclosure of the invention, for a given duration under prescribed conditions.

There seems no substantial difference among all three Offices that the disclosure of the invention must fulfill certain formal and substantive requirements since it is a medium for the protection and utilization of the invention, in other words, it plays a role both as a technical literature disclosing the technical details of the invention and as a patent right document accurately defining the scope of a patent.

2. Description of the invention

(1) Matters to be stated in the description and their arrangement

All three Offices coincide in that the application must include "title of the invention", "description of the invention", "claim(s)", "the drawings (if drawings are accompanied)".

In all three Offices, an "abstract" is required.

With regard to the required matters to be stated in the description, "Industrial Field of Utilization" (JPO; “Technical Field to which an Invention Pertains”, EPO; "the technical field to which the invention relates", USPTO; "field of the invention"), "Prior Art" (EPO; "the background art"), "Working Examples" (where preferable) and a brief explanation of the drawings are required by all three Offices.

In JPO and EPO, "Problem to be Solved by the Invention" (EPO; "the technical problem") and "Means for Solving a Technical Problems" (EPO; "its solution") should be included in or deducible from the specification (EPO).

In EPO, "any advantageous effects of the invention" should be stated.

USPTO, however, makes no comment about effects of the invention. In USPTO, "cross-references to related applications (if any)" should be included in disclosure.

In all three Offices, arrangement of the matters to be stated in the description is prescribed in Regulations.

The order of presentation of the various matters set out in regulations or MPEP need not be strictly adhered to in all three Offices.

Further, JPO and USPTO coincide in that each of the lettered items should be

preceded, by the headings indicated. In EPO, on the other hand, titles or headings are not required but may stand if supplied though they should preferably be deleted.

(2) Title of the invention

There is no difference among all three Offices in that the "title of the invention" should be such as to indicate clearly and concisely the invention concerned.

In EPO, the title may be amended at grant to reflect any changes in claim categories, if this is thought necessary. The requirement that the title of the invention be taken from the Request for grant and restated at the beginning of the description has been deleted.

(3) Explanation of the invention

(i) Technical field, industrial field of the utilization

JPO states that as “Technical Field to which an Invention Pertains,” at least one technical field to which a claimed invention pertains should be stated in a specification.

EPO states that a general indication of the technical field (here take to be synonymous with industrial field of utilization) is required in the description.

In USPTO, the field of the invention is recited in the background of the invention, and it may include a paraphrasing of the applicable U.S. patent classification definitions.

(ii) Prior art, background art

The practices of all three Offices coincide on the point that the description of the prior art related to the invention is required.

In USPTO, the description may include references to specific prior art or other information where appropriate. EPO requires a reference to the pertinent documents together with a brief summary of the relevant contents.

USPTO follows the practice that prior arts should be described in such a way as concretely pointing out their problems, EPO, similarly, requests the reason for the inclusion of the reference to be indicated.

JPO states that the detailed description of the invention shall provide the source of the information concerning the invention(s) known to the public through publication such as the name of the publication and others where the person requesting the grant

of a patent has knowledge of any invention(s) related to the said invention, that has been known to the public through publication at the time of filing of the patent application.

(iii) Problems which the invention aims to solve

JPO comments that as "Problem to be Solved by the Invention," an application should state at least one technical problem to be solved by a claimed invention.

In EPO and USPTO, the problems involved in the prior art or problems which are solved by applicant's invention should be evident or indicated, where applicable. The applicants are not obliged to explicitly state those problems.

USPTO also states that there is no requirement that applicant even be aware of the problems with the prior art.

(iv) Disclosure of the invention (means of solving the problems)
– enablement requirement

EPO states that enablement is taken to mean the ability of the person skilled in the art to perform the invention on the basis of the information supplied in the description.

USPTO states that the requirements of how to make and how to use the invention have become referred to in combination as the "enablement requirement".

Accordingly, in USPTO, applicant is required to set forth the steps and/or apparatus for carrying out the invention in the disclosure. In EPO, the description must disclose any feature essential for carrying out the invention so that the skilled person can put the invention into practice without undue effort.

In JPO, the detailed description of the invention shall be described in such a manner that a person skilled in the art to which the invention pertains can carry out the claimed invention.

(a) Amount of detail needed to satisfy the sufficiency of description requirement
– functional vs. structural description.

In EPO, as a rule, it is necessary that the invention is described in terms of functional or structural statements.

In USPTO, applicant may describe the invention in both functional and structural statements. USPTO does not prefer one form of statement over the other as long as the

invention is sufficiently described. U.S. law contains no requirement for structural disclosure.

JPO states that, in the case of “an invention of a product,” various forms of expression such as function and others can be used as matters to define an invention in addition to the forms of expression such as combination of products or the structure of products.

In EPO, for some technical fields (e.g. computers), it is considered that a clear description of the function may be much more appropriate than an over-detailed description of structure. For claims directed to a further therapeutic application of a known substance or composition where the condition to be treated is defined in functional terms, the claim will be regarded as clear only if instructions, in the form of experimental tests or testable criteria, are available from the patent documents or from the common general knowledge allowing the skilled person to recognise which conditions fall within the functional definition and accordingly within the scope of the claim.

(b) Definition of "person skilled in the art"
– whether the same as for inventive step

In JPO, the term "a person having ordinary skill in the art" is considered to mean a person who has ability to use ordinary technical means for research and development (including comprehension of document, experimentation, analysis and manufacture) and to exercise ordinary creativity in the art to which the invention pertains on the assessing sufficiency of the description.

Also, the term "a person having ordinary skill in the art" is considered to mean a person who has the common general knowledge in the art to which the claimed invention pertains at the time of filing of an application, and has ability to use ordinary technical means for research and development, who has ability to exercise ordinary creativity in selecting materials and changing designs, and who is able to comprehend as his/her own knowledge all technical matters in the state of the art in the field to which a claimed invention pertains at the time of filing a patent application on the assessing inventive step.

EPO states that there is no expressional difference in the definition of the person skilled in the art between the assessing inventive step and the assessing sufficiency of the description. In EPO, for assessing inventive step, the person skilled in the art is expected to have access to all the relevant documents in the state of the art. However,

in determining the sufficiency of the description this same person should not be expected to undertake any search to obtain necessary information missing from the description itself.

In USPTO, on the definition of the person skilled in the art, although, similar language is employed under Section 103 or Section 102, there is a difference in the level of skill attributable to a person in the art depending on whether the attribution is occurring under two sections. The difference in attribution of skill level results from the art that is available to skilled persons under each section. The pool of available art is greater on the assessing inventive step than available to prove enablement on the assessing sufficiency of the description.

– relevant art

In EPO, the "relevant art" covers not only the teaching of the application itself and the references therein, but also what was common general knowledge in the art at the date of filing the application. "Common general knowledge" refers to the information contained in basic handbooks, monographs and textbooks on the subject in question. As an exception, it may include information contained in patent specifications or scientific publications, if the invention lies in a field of research which is so new that the relevant technical knowledge is not yet available from textbooks.

In USPTO, the relevant art is not only the art where the problem has arisen or where the solution to the problem is found, but also the art which would afford the "best chance" of enablement. Relevant art for enablement must be readily available and known to one of ordinary skill in the art prior to the filing date of the application. In contrast, for inventive step purposes, relevant art does not have these restriction.

– use of prior art in the determining enablement

In JPO, the detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing.

In EPO, the person skilled in the art is expected to depend on common general knowledge in the art for obtaining necessary information missing from the description itself, but should not be expected to undertake any search. He is assumed, however, to have had at his disposal the means and the capacity for routine work and

experimentation, which are normal for the technical field in question.

In USPTO, the prior art used in the determining enablement must be readily available and known to one skilled in the art as of the date of filing of the application.

(c) Incorporation by reference

In JPO, the detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing.

In EPO, on referring to any prior art document, incorporation of the whole or part of its content by a mere reference and/or by mere stating that its content is incorporated is not allowed where the reference relates directly to the disclosure of the invention. Under these circumstances at least a summary of the document should be incorporated explicitly in the description. The new version of the European Patent Convention ("EPC 2000", which is deemed to enter into force on December 13, 2007 at the very latest) explicitly allows incorporation by reference of the description and any drawings of a single earlier application, provided the earlier application is clearly identified, already available in /or made available to/ EPO in one of the official languages of EPO. The applicant also has the option of indicating that he wishes the claims of the earlier application to take the place of the claims in the application as filed. Such an indication must be made on the date of filing,

In USPTO, the criteria for incorporation of material are set forth in 37 CFR 1.57(b) and MPEP 608.01(p) and are dependent upon whether the material is considered "essential", or "nonessential". An application for a patent when filed may incorporate "essential material" ("essential material" is defined in 37 CFR 1.57(c) as that which is necessary (1) to provide a written description as required by 35 U.S.C. 112, first paragraph, (2) to describe the invention as required by 35 U.S.C. 112, second paragraph, or (3) to describe the structure, material or acts that correspond to a claimed means or step for performing a specified function as required by 35 U.S.C. 112, sixth paragraph.) by reference to a United States patent or a U.S. patent application publication. Nonessential subject matter may be incorporated by reference to patents or applications published by the U.S., foreign countries or regional patent Offices; prior and concurrently filed commonly owned U.S. applications; or non-patent publications. An incorporation by reference by hyperlink or other form of browser executable code is not permitted. In addition, 37 CFR 1.57(a) provides that , if all or a portion of the

specification or drawing(s) is inadvertently omitted from an application, but the application contains a claim under 37 CFR 1.55 for priority to a prior-filed foreign application, or a claim under 37 CFR 1.78 for the benefit of a prior-filed provisional, nonprovisional, or international application, that was present on the filing date of the application, and the inadvertently omitted portion of the specification or drawing(s) is completely contained in the prior-filed application, the claim for priority or benefit shall be considered an incorporation by reference of the prior-filed application as to the inadvertently omitted portion of the specification or drawings. See MPEP 201.17.

(d) Risk of the future "unenablement"

There is no difference among all three Offices on the following points that using trademark or registered trademark in description with risk of future unenablement is insufficient for enablement requirement, and that such using may be rejected.

EPO and USPTO point out that there is a risk of future unenablement, where the invention relies on deposited microorganism.

(e) Disclosure requiring experimentation
– reasonable experimentation
– unreasonable experimentation

JPO states that the detailed description of the invention shall be described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the specification and drawings taking into consideration the common general knowledge as of the filing.

Therefore, if “a person skilled in the art” who is supposed to have ordinary skill cannot understand how to carry out the invention on the basis of teachings in the specification and drawings taking into consideration the common general knowledge as of the filing, then, such a description of the invention should be deemed insufficient for enabling such a person to carry out the invention. For example, if a large amount of trials and errors or complicated experimentation are needed to find a way to carry out the invention beyond the reasonable extent that can be expected from a person skilled in the art, such a description should not be deemed sufficient.

EPO states that no undue effort is to be expected from the skilled person either by way of search or experimentation. However, experimentation that leads to a quick and reliable way of obtaining the desired result is a reasonable expectation where the

manner and outcome of such experimentation is described. Similarly, routine methods of experimentation or analysis extending the particular teaching of the description to cover the whole field claimed can be expected of the skilled reader. Where the successful performance of an invention depends on chance, the description is held to be insufficient. The description of alleged inventions working contrary to established physical laws is also held to be insufficient.

USPTO states that it is not fatal if some experimentation is required in order for one skilled in the art to actually practice the invention so long as undue or unreasonable experimentation is not required. The determination of what constitutes undue experimentation in a given case requires the application of a Standards of reasonableness and will depend on the facts of each case. The following factors may be considered in determining whether the experimentation required was undue or unreasonable (*In re Wands*):

(1) the quantity of experimentation needed to make or use the invention based on the content of the disclosure;
(2) the amount of direction provided by the inventor;
(3) the existence of working examples;
(4) the nature of the invention;
(5) the state of the prior art;
(6) the level of one of ordinary skill;
(7) the level of predictability in the art; and
(8) the breadth of the claims

The minutiae of descriptions or procedures perfectly obvious to one of ordinary skill in the art yet unfamiliar to laymen need not be set forth.

(f) <u>How to make</u>

<u>– availability of starting materials</u>

There is no substantial difference among all three Offices on the following point that apparatus, methods or materials essential to make the inventive product or carry out the inventive process must be adequately disclosed.

In JPO, for an invention of a process for manufacturing a product, the description shall be stated so as to enable a person skilled in the art to manufacture the product by using the process. Thus, i) materials, ii) process steps and iii) final products shall in principle be described in such a manner that a person skilled in the art can manufacture the product when taking into account the overall descriptions of the

specification, drawings and the common general knowledge as of the filing.

Under USPTO practice, a microorganism which provides an essential starting material or acts to transform an initial material into the desired product must be placed in a permanent culture collection and be made available to the public once a patent issues in order to comply with the how to make aspect of the enablement requirement.

(g) How to use
– utility and operability

JPO states that for an invention of a product, the description shall be stated in the detailed description of the invention so as to enable a person skilled in the art to use the product. To meet this, the way of using the product shall be concretely described except where the product could be used by a person skilled in the art without such explicit description when taking into account the overall descriptions of the specification, drawings and the common general knowledge as of the filing.

EPO states that the description should indicate explicitly the way in which the invention is capable of industrial exploitation when this is not self-evident.

USPTO states that 35 U.S.C 101 sets forth that in order to be patentable the invention must be useful. A rejection under Section 101 for lack of utility will necessarily entail a rejection under Section 112, first paragraph in that if the invention lacks utility the specification cannot have taught how to use the invention.

There is no difference among all three Offices in that the invention must be useful.

(h) Proof of enablement

In JPO, where an examiner makes a notice of reason for refusal on the ground of violation of enablement requirement under Article 36(4)(i), (s)he shall identify the claim which violates the requirement, make clear that the ground of refusal is not a violation of Ministerial Ordinance requirement but a violation of enablement requirement under Article 36(4)(i), and point out particular descriptions, if any, which mainly constitute the violation. When sending a notice of reason for refusal, the examiner should specifically point out a concrete reason why the application violates the enablement requirement.

The reason above should be supported by reference documents. Such documents are, in principle, limited to those that are known to a person skilled in the art as of the

filing. However, specifications of later applications, certificates of experimental result, written oppositions to the grant of a patent, and written arguments submitted by the applicant for another application etc. can be referred to for the purpose of pointing out that the violation stems from the descriptions in the specification and drawings being inconsistent with a fact generally accepted as scientifically or technically correct by a person skilled in the art.

Against the notice of reason for refusal on violation of enablement requirement, an applicant may argue or clarify by putting forth written arguments or experimental results, etc.

In EPO, where there are well-founded reasons to believe that a skilled person would not be able to extend the teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis, then the applicants are called on to furnish convincing evidence to the contrary or to restrict their claims accordingly. Such reasons should preferably be supported by a document.

In USPTO practice, it is the USPTO that has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling. The statements must be taken as in compliance unless there is reason to doubt the objective truth of the statements. It is not required that a specification convince persons skilled in the art that the assertions therein are correct. The applicant may subsequently provide affidavit evidence not for the purpose of correcting any deficiency in the original disclosure but to prove that the disclosure originally provided was in fact enabling.

(v) Action or working of the invention

In JPO, it is required to describe how each matter defining the invention of the product works (role of each matter) (namely, "operation" of each matter) if a person skilled in the art needs it for using the product of an invention.

In EPO, it is expected that the description teaches how the invention works. No statement of any underlying theory or principle is required.

In USPTO, while the specification must be specific enough to enable one skilled in the art to practice the invention, it is not required that the theory or scientific principle underlying the invention be explained.

(vi) Working examples (Best mode of practicing the invention)

EPO states that at least one specific way of performing the invention must be described.

In USPTO practice, there is not necessarily a relationship between the presence of a working example in the specification and the requirement to disclose the best mode. A working example may or may not represent the best mode. Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted.

In JPO, when embodiments or working examples are necessary in order to explain the invention in such a way that a person skilled in the art can carry out the invention, “the mode for carrying out the invention" should be described in terms of embodiments or working examples. In cases where it is possible to explain the invention so as to enable a person skilled in the art to carry out the invention, neither embodiments nor working examples are necessary.

(a) <u>What is a mode</u>

In JPO, at least one mode that an applicant considers to be the best among the “Modes for Carrying out the Invention” showing how to carry out the claimed invention in compliance with the requirements in Article 36(4)(i) should be described in the detailed description of the invention. However, it is proper to describe the mode that an applicant considers to be the best about the modes for carrying out the invention in terms of the requirements in Article 36(4)(i). Even if it is clear not to describe the mode that an applicant considers to be the best, it does not constitute a reason for refusal.

In EPO, a "mode" is taken to mean "manner" or "way". To be valid, the mode or way of carrying out the invention-as described must lie within the scope of the broadest claim.

In USPTO, 35 U.S.C. 112, first paragraph requires that, the specification "shall set forth the best mode of carrying out" the invention. The requirement for disclosure of a best mode is a question separate and distinct from the question of how to make and use the invention. Nonenablement is the failure to disclose any mode. If an invention pertains to an art where the results are predictable, a broad claim can be enabled by disclosure of any single embodiment. However, should an alternative embodiment than that disclosed be known to be superior the failure to disclose that alternative would

result in a fatally defective disclosure under the best mode requirement of Section 112 notwithstanding applicant's compliance with the enablement requirement. While the enablement requirement may be satisfied by consideration of the level of skill in the art, the best mode requirement requires explicit disclosure of that which the inventor contemplates as the preferred embodiment.

(b) Best mode contemplated by inventor

In JPO, it is proper to describe the mode that an applicant considers to be the best about the modes for carrying out the invention in terms of the requirements in Article 36(4)(i). However, even if it is clear not to describe the mode that an applicant considers to be the best, it does not constitute a reason for refusal.

EPO mentions that there is no requirement in the EPC to describe the best way of performing the invention.

USPTO states that the purpose of this requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which have in fact conceived. How an inventor should disclose the best mode is left to the inventor. While the best mode must be disclosed it need not be so labeled. Whether the best mode has been adequately disclosed is subject to review and is a question of fact. However, as there is no objective standard by which to judge the adequacy of a best mode disclosure only evidence of concealment (accidental or intentional) will be considered. That evidence, in order to result in affirmance of a best mode rejection, must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment. Such possibility exists even though there may be a general reference to the best mode. Improvements in the invention made by another that represent the best mode for carrying out the invention must be disclosed by the inventor if known to him at the time of filing the application.

(c) Critical date with regard to disclosing best mode
– continuing applications (i.e. Must applicant disclose a better mode discovered in the interim ?)

JPO and EPO make no comment on this item.

In USPTO, the critical date with regard to disclosing a best mode is the best mode contemplated as of the date of filing of the application. Hence, subsequent discovery of

a best mode need not be disclosed in an application previously filed. Whether the inventor must disclose a best mode discovered subsequent to the filing of the parent application in a continuation or continuation-in-part application is still not settled in U.S. case law. For a U.S. application to be accorded the benefit of the filing date of a foreign application under 35 U.S.C. 119(a) the foreign application must satisfy the requirements of Section 112, first paragraph. (Utility and how to use requirements under Section 112, first paragraph were in issue). The foreign priority application must also comply with the best mode requirement under Section 112, first paragraph in order for the U.S. application to be accorded the priority date of the foreign application. Additionally, the U.S application must disclose any best mode discovered subsequent to the filing of the foreign priority application.

(vii) Advantageous effects or merits of the invention

In JPO, an applicant should describe an advantageous effect of a claimed invention over the relevant prior art, if any, as far as (s)he knows.

In EPO, any advantageous effects of the invention with respect to the background art should be stated.

By contrast with these, in USPTO, the specification explains the invention by customarily comparing the invention with the prior art, and in so doing, gives the improvements over the prior art. However, U.S. law does not require applicant to explain the invention in terms of (1) "problem-solution" or (2) the advantageous effects" or "merits of the invention." Any discussion in the specification which infers a statement as to the problem with the prior art; the solution of the problem, an advantageous effect; or, the merits of the invention is not to be construed as requiring these items. A U.S. examiner will not require applicant to amend the specification to supply any of these items. The phrases "advantageous effects" or "merits of the invention" are not a phrase of art for U.S. practice.

(viii) Industrial applicability

JPO and EPO coincide in that industrial applicability of a claimed invention must be shown in or evident from the specification as a rule.

In JPO, industrial applicability is indicated, only when it is not clear from the description of the nature of invention, specification, etc. Industrial applicability is clear from the description of the nature of invention, specification, etc. in many cases, and

need not to be described explicitly in these cases.

EPO states that industrial applicability is defined in Article 57 EPC:

"An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are now considered as matter excluded from patentability under Article 53(c) EPC 2000 ("Exceptions to patentability") and no more as "matter not to be regarded as inventions which are susceptible of industrial application".

In USPTO, 35 U.S.C 101 requires that the invention sought to be patented be "useful." To comply with the utility requirement an invention need not be superior to that which is already known. Utility questions in USPTO practice arise when a claimed invention does not have a well-established utility and applicant fails to assert a specific, substantial, and credible utility for the claimed invention in the specification. The credibility prong of the utility requirement is at issue when, for example, an asserted utility would violate a scientific principle or a claimed invention would be inoperative (e.g., a perpetual motion device). More frequently, utility issues arise in the context of the requirement for a specific and substantial credible utility in applications disclosing chemical and biological materials (MPEP 2107.01). A "specific" utility is a utility that is specific to the subject matter claimed and can provide a well-defined and particular benefit to the public. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Regarding the "substantial" utility prong, an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. An asserted use must show that the claimed invention has a significant and presently available public benefit.

(4) Brief description of the drawings

All three Offices coincide in that a brief description of the drawings is required, when there are drawings.

3. Claims

(1) General

JPO states that the scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent, EPO states that the claim(s) define the matter for which protection is sought, and USPTO states that the claim must particularly point out and clearly define the subject matter of the invention.

In EPO, the applicant will have the option of incorporating by reference the claims of a single earlier application under the new version of the EPC ("EPC 2000"). The indication that he wishes the claims of the earlier application to take the place of the claims in the application as filed must be made on the date of filing.

Japanese Patent Act provides that the technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application, and USPTO comments and EPO agrees that there are two purposes for a claim - patentability and infringement determinations.

(2) Claiming format

(a) Number of claims

All three Offices permit multiple claims.

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

However, the EPC Rules provide that several independent claims in the same category are allowable only where it is not appropriate, having regard to the subject-

matter of the application, to cover this subject-matter by a single claim.

In JPO, claims are not limited in number, provided that requirements for unity of invention are met.

(b) Structure of claims (e.g. Markush claims, Jepson type claims)

The EPO practice is that two-part form of claims is recommended when it is appropriate, USPTO comments that there are three portions to the structure of a claim: the preamble, the transitional phrase and the body.

Concerning Jepson type claims, USPTO comments that it is necessary to set forth the prior art in the claim preamble part of the claim which is followed by the new or improved portion of the invention.

EPO has some reservations concerning "Jepson type claims", but states that "two-part form of claims" shall contain a statement indicating the technical features which are part of the prior art and a characterizing portion stating the technical features which it is desired to protect.

So there is no fundamental difference between EPO and USPTO.

Markush type claim is an accepted format of claims for all three Offices.

The practice on Markush claiming has already been agreed on the Trilateral Harmonization Project 12.1.

(c) Categories

A difference does exist among all three Offices as to the division of the categories.

JPO states that categories of inventions are divided into two main categories i.e. an invention of a product and an invention of a process. A category of an invention of a process includes an invention of a process for manufacturing products.

EPO defines two basic categories of claims:

– claims for physical entities and

– claims for activities.

The first category can be further subdivided into apparatus and products, and the second one into process and use.

USPTO divides the categories of inventions into four categories: process, machine, manufacture and composition of matter.

(d) Independent and dependent claims

JPO mentions that independent form claims and dependent form claims differ only in the form of description, and are treated in the same manner.

EPO comments that an independent claim is a claim which stands on its own, without referring to any other claim. It should contain all the essential features of the invention. EPO defines a dependent claim as "any claim which includes all the features of any other claim." To be considered as dependent a claim should be in the same category as the claim to which it refers back. A claim which refers back to another claim in a different category is considered an independent claim.

USPTO points out that applicant is permitted to claim an invention by presenting one or more claims in independent and dependent form. Effective November 1, 2007, the rules of practice in the USPTO for the examination of claims in an application (37 CFR 1.75) has been revised to provide that if the number of independent claims is greater than 5 or the number of total claims is greater than 25, the USPTO will require the applicant to submit an examination support document (ESD) complying with 37 CFR 1.265 covering all of the claims in the application. If applicant chooses not to file an ESD, the application must be amended to contain no more than 5 independent claims and no more than 25 total claims. In addition, 37 CFR 1.75(b)(2) has been amended to state that a claim that refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim for purposes of 37 CFR 1.75(b) and for fee calculation purposes. A claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for purposes of 37 CFR 1.75(b) and for fee calculation purposes. [Note: In view of the preliminary injunction issued by the U.S. District Court for the Eastern District of VA on Oct. 31, 2007, the changes to the rules of practices in the claims and continuation final rules did not go into effect on Nov. 1, 2007.]

All three Offices permit claims referring back to one or more claims.

However, in USPTO, multiple dependent claims may not depend, either directly or indirectly, upon any other multiple dependent claims.

(e) Arrangement of claims

USPTO prefers applicant to arrange the claims in order of scope, so that the first claim presented is the broadest and the last, the most detailed.

On the other hand, in EPO, there is no legal requirement that the first claim should be the broadest.

All three Offices state that the claims must be numbered consecutively in Arabic numerals.

JPO comments that when a claim refers to another claim, the claim shall not precede the other claim to which it refers.

EPO states that all dependent claims shall be grouped together to the extent and in the most appropriate way possible.

USPTO mentions that dependent claims should be arranged closest to the claim or claims from which they depend.

(3) Contents of claims

(a) Indication of technical features of the invention

In JPO, the scope of claims shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent.

EPO states that the claims shall define the matter for which protection is sought in terms of the technical features of the invention. Independent claims should contain all the essential features of the invention. Mentioning results or effects of technical features is allowable.

In USPTO, the phrase "technical features" is not a phrase of art for U.S. claiming practice, and USPTO emphasizes that applicant is permitted to claim the subject matter "which the applicant regards as his invention". The U.S. examiner may not require that an "indispensable constituent feature" or an "essential technical feature" be added to the claim.

(b) Indication of non-technical matters

JPO states that if non-technical matter is stated in a claim as a whole as a result of existence of such statements as sales area or distributors, the description of the claims is considered not to comply with the requirements of Article 36(6)(ii) of the Patent Act.

EPO cites commercial advantages as a non-technical matter which should not be contained in the claims.

On the other hand, USPTO states that the phrases "non-technical matters" or "non-technical features" are not phrases of art for U.S. claiming practice. U.S. law and/or practice do not require the applicant to identify the limitations in terms of technical

features and non-technical features.

(c) Indication of purpose

JPO states that there is no requirement to describe the purpose.

In EPO, when the claim is for a physical entity an indication of the purpose may have a limiting effect on the scope of the patented matter.

U.S. law does not recognize the word "purpose" as a term of art. U.S. law does not provide that the purpose must be included as a limitation in a claim.

(d) Limitation on function

JPO states that when the claim includes matters defining a product by its function or characteristics, etc., the scope of the invention cannot necessarily be clear and an invention for which a patent is sought may not be clearly identified.

EPO sees no special aspect to comment on.

In USPTO, there is no prohibition against the inclusion of functional language in a claim, however, functional language is objectionable in a claim when the language is not precise and definite in defining the invention and the language has a scope of protection beyond what is disclosed in the specification.

(e) Definition by function

JPO states that when the claim includes matters defining a product by its function or characteristics, etc., the scope of the invention cannot necessarily be clear and an invention for which a patent is sought may not be clearly identified.

EPO mentions that functional terms used in claims are in fact considered as being technical features expressed in a different way, and that "functional limitations may be included provided that a skilled man would have no difficulty in providing some means of performing this function without exercising inventive skill". Therefore, EPO permits functional terms used in claims. However, a technical result may be defined by functional features in a claim only if, from an objective point of view, such features could not otherwise be defined more precisely without restricting the scope of the invention, and the features provide clear and sufficient instruction for the expert to reduce invention to practice without undue burden (T 68/85, OJ 1987, 228, which developed into established case law).

There is no prohibition in U.S. law against the use of functional language in claims. In addition, USPTO provides that an element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

(f) Definition of terms

The reports of EPO and USPTO coincide in that terms shall be used both in their ordinary sense and consistently throughout the specification and be defined where a term is used for a particular meaning.

In JPO, where the statement in a claim are deemed unclear by itself, the examiner should examine whether a term in the claim is defined or explained in the specification and drawings, and should evaluate whether such definition or explanation, if any, makes the claim statements clear by considering the common general knowledge as of the filing.

EPO states that when a word in a claim is given a special meaning, this should be made clear as far as possible already in the claim itself, because only the claims will be published in the three official languages of EPO.

JPO admits that with respect to microorganisms, substances with foreign names, the meaning of which is difficult to be fully expressed in Japanese, scientific literature in a foreign language, etc., the name thereof in Japanese shall be followed by words in the original language in parentheses.

(g) Description in alternative form

EPO and USPTO coincide in that alternative expressions are permitted in a claim provided that the criterion of clarity is satisfied, and that there is no commonly accepted generic expression. Alternative expressions are permitted in a claim provided that the expressed elements have to be basically equivalents for the use in the invention. However, EPO does not permit the same feature to be referred to in different ways in the claim. These are not held to be true (i.e. mutually exclusive) alternatives but represent inconsistent terminology. A Markush claim is permitted in all three Offices.

In JPO, if there are expressions where optionally added items or selective items

are described along with such words as “when desired,” “if necessary,” etc., there are some cases that the description of the claims is not clear.

(h) Use of ambiguous terms (e.g. definition by terms indicating extent)

JPO and EPO coincide in that ambiguous terms indicating extent shall not be used when writing the claim, as a rule.

In EPO, it is recommended not to use relative terms, terms expressing approximation or any ambiguous expressions, unless they have a well-recognized meaning in the relevant technical field.

JPO takes a similar practice. That is to say, if there are expressions where the standard or degree of comparison is unclear such as “with slightly greater specific gravity,” “much bigger,” “low temperature,” “high temperature,” “hard to slip,” “easy to slip” or where the meaning of the term is unclear, there are some cases that the scope of the invention is not clear.

On the other hand, USPTO comments that terms indicating extent do not automatically render a claim invalid due to indefiniteness. Further, in USPTO practice, when a word of degree is used with a claim limitation, the examiner must determine if the specification provides some standard for measuring that degree and if one skilled in the art can determine whether a product or process falls within the language of a claim.

(i) Claims attempting to define the invention by objectives to be attained

EPO comments that the claims should not be totally defined by the objective to be reached.

However, EPO states that in combination with other features of a technical nature, the use of a result to be achieved as one of the characteristics of the invention may be allowed when no other way exists to define the invention.

JPO states that where the claim includes the definition of a product by the result to be achieved, there may be cases where concrete products which can obtain such result can not be conceived. When a certain concrete means which can obtain such result is disclosed in the specification or drawings and it is also recognized that only the said concrete means is substantially disclosed, the scope of the invention is usually deemed unclear.

U.S. law does not require the claim to define the objectives to be attained or prohibit

the claim from doing so. U.S. law would permit the objective to be recited in the claim but would evaluate the claim to ensure that the claim is definite in defining the invention and that the language used does not provide a scope of protection beyond what is disclosed in the specification.

(j) Definition using chemical or mathematical equations or formulas

All three Offices coincide in that there is no prohibition against the use of chemical or mathematical equations and formulas in a claim to define the invention. All three Offices also coincide in that a mathematical equation or formula per se, is not patentable subject matter.

In USPTO, where various terms in the mathematical, or chemical equations or formulas have been defined in the specification, there is no requirement to repeat the definition of each term in the body of the claim.

(k) Devices or objects with limitations on their usage

All three Offices coincide in that devices or objects may be claimed with limitations on their usage.

EPO states that the protection conferred by the claim is not interpreted as being limited to the stated use. On the contrary, the claim is interpreted as being for the apparatus or product per se. An exception to this principle applies in the field of medical treatment, where claims directed to a first/further medical use of a known substance or composition are allowable (Article 54(4) and (5) EPC 2000).

The EPO does not allow claims such as “Apparatus for carrying out the process claim 1".

(1) Dependence on references to description of the invention or to drawings

Both JPO and EPO state that the claims shall not depend on references to a detailed description of the invention or to drawings, as a rule. However, when necessary for the understanding of the content of the claims, the reference numerals or signs used in the drawings attached to the request of the application may be indicated in parentheses.

EPO gives two examples of cases where it may exceptionally be accepted to refer to the description or drawings.

The first one is an invention involving some peculiar shape, illustrated by drawings which could not be readily defined in words or by a mathematical formula in the claims.

The other one is for a chemical product some of whose features can be defined only by means of graphs or diagrams.

A further special case is where the invention is characterized by parameters, and the description of the methods of and means for measurement is so long that their inclusion would make the claim unclear or difficult to understand.

There was no comment on this point in the report of USPTO. USPTO explains the interpretation of claims in this item. Claims are construed in light of the specification but limitations from the specification which are not written into the claims are not considered to be present therein. The words used in the claims will be given their ordinary and customary meaning unless it appears that the inventor used them differently. While the claims are construed in light of the specification, it does not mean that the claims incorporate all the disclosed features of the specification which are not recited in the claims. Drawings may be used in the same manner to interpret the claims as the specification.

(m) Others

EPO comments on disclaimer. The purpose of a disclaimer is to limit the scope of a claim, expressly excluding from it an element defined by its technical features. This technique of the disclaimer is very often used in chemistry to exclude elements which do not satisfy all the criteria for patentability, but its use is not in any way limited to chemistry. A disclaimer may however be used only where there is no better way to define the subject-matter of the invention using positive technical features.

(4) Support in description of the invention (extent of disclosure in the description and drawings vs. broadness of claims, e.g. the relationship between the scopes of working examples and claims, or the extent to which addition of working examples is permitted)

(a) Undue breadth

– disclosure problem

– claims reading on inoperative subject matter

All three Offices coincide in that the claims shall be supported by the description.

USPTO comments that 35 U.S.C. 112, first paragraph requires "that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." This does not imply that the claims must be strictly limited to what has been explicitly demonstrated in the specification to be enabling. There is no requirement in USPTO practice that the claims be limited to working examples. See section 3. (3) (1). A claim that is drafted unduly broad vis-à-vis the actual invention may be rejectable under three bases:

1) Claims may be broader than the prior art will permit.
2) If the claims encompass subject matter that the inventor does not in fact regard as part of his invention they would be rejectable under 35 U.S.C. 112, second paragraph which requires that an applicant particularly point out and distinctly claim the subject matter which the applicant regards as his invention.
3) Where a claim encompasses material for which the specification is not enabling along with material for which the specification is enabling the claim would be rejectable under 35 U.S.C. 112, first paragraph.

USPTO comments that all questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enable to make and use the entire scope of the claimed invention without undue experimentation. See MPEP 2164.08. The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. See MPEP 2164.03.

Regarding claims reading on inoperative subject matter, USPTO comments that the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. See

MPEP 2164.08(b). Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable.

In EPO, most patent applications involve a generalization of what the inventors have actually carried out. To allow such a generalization in the description is an accepted practice which is then reflected in the wording of the claims. The key issue is: how broad may the generalization be? This can only be decided on a case by case basis. As a general rule "A fair statement of claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the applicant of a just reward for the disclosure of his invention". As a general rule, "a claim should be regarded as supported by the description unless exceptionally there are well-founded reasons for believing that the skilled man would be unable, on the basis of the information given in the application as filed, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis".

Both EPO and USPTO coincide in that the burden is on the examiner to establish why the result expected could not be reached for a certain part of the subject-matter claimed. In EPO, once the examiner has set out a reasoned case that a claim is not supported over the whole of its breadth, the onus of demonstrating that the claim is fully supported lies with the applicant.

JPO states that typical cases exhibiting nonconformity to the provision of Article 36 (6) (i) are presented as follows;

(i) the matter corresponding to claims is neither stated nor implied in a detailed description of the invention;

(ii) the terms used in claims and those used in a detailed description of the invention are inconsistent, and as a result, the relationship between a claim and a detailed description of the invention is unclear;

(iii) the matter disclosed in a detailed description of the invention cannot be extended and generalized to the scope of the matter in a claimed invention even if taking into account the common general knowledge as of the filing; or

(iv) a means for solving the problems described in a detailed description of the invention is not reflected in the claims, and as a result, a patent beyond the scope described in the detailed description is consequently claimed.

– relationship between working examples and claims

Under JPO practice, extension or generalization based on one or more specific embodiments in a detailed description of the invention is permissible in a claim. The maximum extent of extension or generalization must not go beyond the scope of matters described in a detailed description of the invention. Because the maximum extent varies with characteristics of the technical field, the proper scope shall be set for each application.

EPO states that, according to Article 84 EPC the Claims which define the matter for which protection is sought have to be supported by the description.

Examples are a part of the description. It is however possible for the applicant to provide further examples to support its assertions while the case is pending before the examining/opposition divisions or the Boards of Appeal.

There is no rule, guideline or instruction which, in EPO, would provide the examiners with guidance on how broad Claims may be for instance in relation to the kind and number of working examples. The principle is that the description has to give sufficient information to third parties allowing the subject-matter claimed to be carried out by the man skilled in the art.

Examples help to provide this information, although they might in particular circumstances not be necessary at all. If a claim covers a broad field, however, the description must give a number of examples or describe alternative embodiments or variations extending over the area protected by the claims. In exceptional cases, a very broad claim may be sufficiently exemplified by a limited number of examples or even one example if the application contains sufficient information to allow the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed.

In USPTO practice, the claims are interpreted in light of the disclosure. However, the statement does not mean that the disclosure is used to limit the scope of the claims. Examples that are presented in the disclosure are just that-examples. Examples are used as a guide to instruct the ordinary person skilled in the art in the making or in the operation of the invention. The examples are not read into the claims as limitations which would limit the scope of the coverage. Only the claim limitations are used to measure the extent of the coverage of the invention. A product or process that is not the same as the examples explicitly set forth in the disclosure, would still infringe the claimed invention, if the product or process reads on the literal wording of the claim.

(b) Broadening claims

In JPO, after an amendment is done, if matter defining an invention in claims comes to be outside the scope of matters described in a description, etc. as filed, the amendment is not acceptable.

It is prohibited to make an amendment whereby inventions, of which patentability has been determined in a notice of reasons for refusal, among claimed inventions prior to the amendment, and inventions amended after the notice of reasons for refusal is given do not meet the requirements for unity of invention because they do not have any same or corresponding special technical feature.

The amendment of the scope of claims after the final notice of reasons for refusal shall be limited to those for the following purposes;

(i) the deletion of a claim or claims as provided in Article 36(5);

(ii) restriction of the scope of claims (limited to the cases where the restriction is to restrict matters required to identify the invention stated in a claim or claims under Article 36(5), and the industrial applicability and the problem to be solved of the invention stated in the said claim or claims prior to the amendment are identical with those after the amendment);

(iii) the correction of errors; and

(iv) the clarification of and ambiguous statement (limited to the matters stated in the reasons for refusal in the notice of reasons for refusal).

EPO states that any broadening of the claims should not extend beyond the content of the application as filed, and amendments to the claims of the granted patent may only be allowed if these do not extend the protection conferred by the claims as granted.

USPTO states that generally, an applicant may claim his invention as broad as the prior art and his disclosure will allow and the applicant may broaden any claim during prosecution of the application. However, under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. "Broadening a claim does not add new matter to the disclosure" so long as the disclosure as originally filed supports the amended claim.

(c) Narrowing and sub-generic claims

Narrowing and sub-generic claims are permitted in all three Offices, as a rule.

EPO states that it might of course occur that the generic claim is supported by the description although direct support is lacking for a particular sub-generic claim. EPO allows sub-generic claims provided that these are supported by the original description.

In USPTO, in the particular instance wherein a genus and several species are originally believed by an applicant to be patentable and wherein it is later determined during examination that at least one species and therefore the genus are unpatentable over the prior art the applicant may cancel the genus and the known species while continuing to claim the other species which are not taught by the prior art.

In JPO, if matter, which is not described in a description, etc. as filed, is singled out, as a result of an amendment to be conceptually specific (for example, matter defining an invention in claims is added), the amendment cannot be construed to be done within the scope of matters described in a description, etc. as filed.

4. Drawings

(1) Substantive questions (e.g. status of drawings as art of the disclosure)

All three Offices coincide in that drawings are regarded as a part of the disclosure. There is no difference among all three Offices that the applicant shall furnish a drawing where necessary for the understanding of the subject matter to be patented.

In USPTO, if it is determined by USPTO at the time of filing or later during examination, that a drawing is necessary for the understanding of the invention then applicant will be notified that the application is incomplete and that a filing date cannot be given. The filing date of the application will be date on which the drawings are filed.

(2) Formal requirements

All three Offices coincide in that the formal requirements of the drawings are dealt with in Regulations.

Detailed comparative analysis has not been made, because it is not considered necessary useful to do it and at present. It will be done when it becomes necessary.

(3) Photographs in lieu of drawings (i.e. their status, categories accepted, conditions of acceptance, etc.)

The practices of all three Offices coincide in the following points.

(1) Photographs are not acceptable in principle.

(2) Photographs can only exceptionally be allowed. They are allowed where drawings are not sufficient to illustrate the invention or where the photographs contain information which cannot be expressed in a different manner.

(3) Even in this case, the photograph shall be sufficiently clear.

For a color photograph, JPO states that a color photograph is not acceptable except that it is attached as a photograph for reference.

USPTO states that black and white photographs submitted in lieu of ink drawings must comply with 37 CFR 1.84(b). Limited use of color drawings or color photographs is provided for in 37 CFR 1.84(a)(2) and (b)(2).

EPO would accept black/white photographs, but not color photographs.

5. Abstract

In all three Offices, it is required to submit an abstract. The practices of the all three Offices accord in the following points.

(1) It should be a concise summary of the disclosure, and the content of the abstract should be such as to enable the reader to ascertain quickly the character of the subject matter covered by the technical disclosure.

(2) The abstract should be drafted by applicants.

In the EPO and JPO, the abstract shall not be used for interpreting the scope of the claims.

If the abstract does not comply with the guidelines, it may be amended by the search examiner (in EPO), the examiner should point out the defect, and require compliance with the guidelines (in USPTO).

6. Requirements for Disclosure and Claims in Special Fields

(1) Computer program deposits

Both JPO and EPO coincide in that an applicant is not obliged to submit a program list but may do so.

JPO states that, in principle, program listings should not be included in the specification or drawings. However, if they are short excerpts written in a computer language generally known to a person skilled in the art and helpful for understanding the invention, such listings are allowed to be included. (“Program

listings" can be submitted and filed as reference material. However, the specification cannot be amended on the basis of such reference material.)

EPO states that the EPC requires the description to be in writing and no exception exists allowing the disclosure through a mere deposit of a computer program.

In USPTO the submission of computer program listings is governed by 37 CFR 1.96. A computer program listing, as used in the rule, means the printout that lists, in proper sequence, the instructions, routines, and other contents of a program for a computer. The listing may be either in machine or machine-dependent (object or source) programming language which will cause a computer to perform a desired task, such as solving a problem, regulating the flow of work in computer, or controlling or monitoring events. The general description of the computer program listing will appear in the specification while the computer program listing may appear either directly or as a computer program listing on compact disc appendix to the specification and be incorporated into the specification by reference. The requirements for sufficient disclosure of inventions involving computer programming is the same as for all inventions sought to be patented. Namely, there must be an adequate written description, the original disclosure should be sufficiently enabling to permit one skilled in the art to make and use the invention as claimed, and there must be presentation of the best mode for carrying out the invention. Sufficiency of disclosure issues in computer cases necessarily will require an inquiry into both the sufficiency of the disclosed hardware as well as the disclosed software due to the interrelationship and interdependence of computer hardware and software. The guidelines for determining sufficiency of disclosure are set forth in MPEP 2106.01. The manner of claiming inventions involving computer programs, like all other inventions, is governed by 35 U.S.C. 112, second paragraph. The claims must accurately define the invention and the specification must describe and identify the combinations of elements which perform the functions noted in the claims.

(2) Chemistry

JPO states that in the case of an invention of a chemical compound, for in stance, the invention should be deemed as clearly explained if the chemical compound is expressed either by name or by chemical structural formula.

USPTO states that USPTO chemical patent practice has raised issues not

generally considered in regard to mechanical or electrical matters or at least not considered to the same degree or frequency. Questions of industrial applicability may be more difficult to decide in regard to chemical matters that encompass chemical intermediates, utility for products where the invention is in the process of their production, type of testing needed to establish utility for drugs and dosage amounts (See section 3. (3) (viii)). An article may be claimed by a process of making it provided it is definite. Where an applicant's product may be incapable of description by product claims as is frequently the case with chemical compositions an applicant is entitled to product-by-process claims that recite the novel process of manufacture (MPEP 2113).

In contrast with these, EPO states that it is not necessary to give the use or effect of new chemical compounds purely for reasons of disclosure.

JPO states that when matters disclosed in a detailed description of the invention cannot be extended or generalized to the scope of matters in a claimed invention even if taking into account common general knowledge as of the filing, the description of the claims is considered not to comply with the requirements of Article 36(6)(i) of the Patent Act.

EPO states that, as a general rule, the examiner should require further evidence in support of a broad claim only when he has strong reasons to believe that the description provides inadequate support for that claim.

USPTO states that support for generic claims based on disclosure of species raises predictability and enablement questions relative to claim scope (See section 3 (4) above).

(3) Micro-biotechnology

In this technical field, all three Offices coincide in the point to allow deposit of micro-organisms as a substitute for the written description.

EPO states that the requirements relating to the deposit of micro-organisms are now set out in detail in Rules 31 to 34 of the Implementing Regulations to the new "EPC 2000".

JPO and USPTO adopt the procedure which follows the Budapest Treaty. When a microorganism used in an invention is not readily available to a person having

ordinary skill in the art, the microorganism must be deposited with a recognized depository authority. There must be a reference to the deposit in the description.

In USPTO, the rules governing deposits of biological materials are set forth in 37 CFR 1.801 to 1.809 (effective January 1, 1990). The issue of the need to make a deposit of biological material typically arises under the enablement requirement of 35 U.S.C. 112, 1st paragraph, the issue could also arise under the description requirement of 35 U.S.C. 112, 1st paragraph, best mode requirement of 35 U.S.C. 112, 1st paragraph, or the requirements of the 2nd paragraph of 35 U.S.C. 112 with respect to the claims. The rule governing the deposit of biological material (37 CFR 1.801) does not attempt to identify what biological material either needs to be or may be deposited to comply with the requirements of 35 U.S.C. 112. For the most part, this issue must be addressed on a case-by-case basis. See MPEP 2403. As noted in 37 CFR 1.801(b), biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112 and that access is not otherwise available in the absence of a deposit. Where a deposit is required to provide the necessary access, a deposit is acceptable for patent purposes only where it is made in accordance with the regulations. Even where access to biological material is required to satisfy the statutory requirement, a deposit may not be necessary if an applicant can show that the biological material is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient. See MPEP 2404.01. Applicant may also show that a deposit is not necessary even though specific biological materials are required to practice the invention if those biological materials can be made or isolated without undue experimentation. See MPEP 2404.02.

In JPO, a person desiring to file a patent application for an invention involving or using a microorganism shall attach to the request a copy of the latest receipt referred to in Rule 7 of the Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (hereinafter referred to as “Treaty”) for the deposit of the microorganism issued by the International Depositary Authority defined in Article 2(viii) of the Treaty, or a document certifying the fact that the microorganism has been deposited with an institution designated by the Commissioner of the Patent Office, except where the

microorganism is readily available to a person skilled in the art to which the invention pertains.

7. Others

(1) New matter / amendments

All three Offices coincide in that they prohibit the introduction of new matter by way of amendment into the disclosure of the invention.

In JPO, it is prohibited to make an amendment whereby inventions, of which patentability has been determined in a notice of reasons for refusal, among claimed inventions prior to the amendment, and inventions amended after the notice of reasons for refusal is given do not meet the requirements for unity of invention because they do not have any same or corresponding special technical feature.

In EPO, a patent application or a patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. During opposition proceedings, amendment in such a way as to extend the protection conferred by the claims as granted is not allowed. Where the protection conferred by the European patent has been extended, this is a ground for revocation.

However, limiting the scope of a claim by using a "disclaimer" that was not disclosed in the application as originally filed may be allowed for restoring novelty over a disclosure in an earlier unpublished European patent application or an accidental anticipation, or for removing subject-matter which is excluded from patentability for non-technical reasons. 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. A disclaimer should remove no more than is necessary either to restore novelty or to disclaim subject-matter excluded from patentability for non-technical reasons. Such disclaimer will never be allowed if it makes a technical contribution to the invention or if the limitation is relevant for assessing inventive step (G 1/03 OJ 8-9/2004, 413) G 2/03 (OJ 8-9/2004, 448)

In USPTO, matter not in the original specification, claims or drawings is usually new matter. When new matter is introduced into the specification, the statement should be objected to under 35 U.S.C. 132 and a requirement made to cancel the new matter clearly identified by the examiner. If the new matter has been entered into the claims or affects the scope of the claims, the claims affected

should be rejected under 35 U.S.C.112, first paragraph, because the new matter is not described in the application as originally filed.

In JPO, the amendment of the scope of claims after the final notice of reasons for refusal shall be limited to those for the following purposes;

(i) the deletion of a claim or claims as provided in Article 36(5);

(ii) restriction of the scope of claims (limited to the cases where the restriction is to restrict matters required to identify the invention stated in a claim or claims under Article 36(5), and the industrial applicability and the problem to be solved of the invention stated in the said claim or claims prior to the amendment are identical with those after the amendment);

(iii) the correction of errors; and

(iv) the clarification of and ambiguous statement (limited to the matters stated in the reasons for refusal in the notice of reasons for refusal).

(2) Specification amendments vs. file wrapper, documents

EPO and USPTO coincide in point that amendments which have been entered are considered to be part of the disclosure of the application to be published.

All three Offices also coincide in that file wrapper documents are available to the public but these documents other than application are not considered to be part of the disclosure of application.

In EPO, amendment by the introduction of further examples or further statements of advantages is not allowed. Such information can, however, be taken into consideration by the examiner when assessing inventive step or whether the invention can be applied over the whole field claimed.

Any supplementary technical information submitted after the filing date of the application will be added to the part of the file which is open to public inspection. From the date on which the information is added to the open part of the file, it forms part of the state of the art for the assessment of novelty. In order to notify the public of the existence of such information submitted after the application was filed, an appropriate mention will be printed on the cover page of the patent specification.

In USPTO, the file wrapper documents include for example, affidavits or declarations filed under 37 CFR 1.131 which are evidence submitted by the applicant to show a completion of the invention in the U.S. before the effective date of the prior art reference so as to overcome the rejection based on the prior art

reference, affidavits or declarations filed under 37 CFR 1.132 which are evidence submitted by the applicant to traverse the grounds of rejection and exhibits accompanying the affidavits or declarations.

(3) Oaths / declarations to overcome rejections

There is a difference among all three Offices.

In JPO, there is no provision for oaths or declarations.

In EPO, sworn statements in writing are admitted as means of giving evidence, but such statements are seldom used in pre-grant proceedings. More often they are submitted in opposition proceedings in order to prove allegations contested by the other party. However, an applicant might supply written information or the production of a document, or produce a sworn statement, either from himself or from an independent witness in support of his own arguments to rebut an allegation by the examiner.

In USPTO, affidavits or declarations which show completion of applicant's invention prior to the filing date of the application are governed by 37 CFR 1.131, affidavits or declarations which traverse the rejection or objection are governed by 37 CFR 1.132, and affidavits or declarations to disqualify commonly owned patent or published application as prior art are governed by 37 CFR 1.130. All affidavits or declarations must be timely presented.

(4) Disclosure requirements for prior art documents

In JPO, the detailed description of the invention shall provide the source of the information concerning the invention(s) known to the public through publication such as the name of the publication and others where the person requesting the grant of a patent has knowledge of any invention(s) related to the said invention, that has been known to the public through publication at the time of filing of the patent application.

EPO comments that the description should mention any background art of which the applicant is aware, and which can be regarded as useful for understanding the invention and its relationship to the prior art; identification of documents reflecting such art, especially patent specifications, should preferably be included. This applies in particular to the background art corresponding to the first or "prior art" portion of the independent claim or claims.

USPTO mentions the contents of the disclosure of the prior art documents. Under USPTO practice, in order to overcome the prior art rejections, an applicant may attack the operability, utility and enablement of the prior art by way of affidavits or declarations under 37 CFR 1.132.

(5) Disclosure requirement for priority documents

In JPO, for saying that the claimed invention of the application claiming priority in Japan is disclosed by the whole application documents of the first application, the claimed invention of the application in Japan understood by consideration of the whole description of the application documents of the application in Japan shall be within the scope of the matters disclosed in the whole filing documents of the first application. It shall be determined whether the claimed invention of the application in Japan is within the scope of the matters disclosed in the whole filing documents of the first application or not, depending on the examples of new matters.

EPO comments that patent application may claim rights of priority based on more than one earlier applications but it is not permitted to mosaic priority documents. In EPO, the basic test to determine whether a claim is entitled to priority is the same as the test of whether an amendment to an application satisfies the requirement of Art. 123 (2) EPC.

USPTO comments that an applicant's foreign application must contain a disclosure of the invention adequate to satisfy the requirements of 35 U.S.C. 112, first paragraph if the later filed U.S. application claiming that invention is to be accorded benefit of the filing date of the foreign application. The disclosure of the invention in the foreign application must be sufficient to enable any person skilled in the art to make and use the invention and must disclose the best mode.

(6) Disclosure requirements for internal priority documents

There are no specific provisions with respect to internal priority in EPO. A priority claim applies equally to earlier European and international applications. There is no provision according to which a European patent application is deemed to be abandoned as soon as it is used to claim priority for a new European patent application, designating at least one identical Contracting State. The applicant is, not allowed to claim in both applications the same invention. However, it is

permissible to allow an applicant to proceed with two applications having the same description if the claims are quite distinct in scope and directed to different inventions.

In JPO, it cannot be said that the claimed invention of the later application claiming priority is disclosed in the description etc. originally attached to the request of the earlier application unless the claimed invention of the later application, which is understood by considering what is disclosed in the description etc. of the later application, is within the scope of matters disclosed in the description etc. originally attached to the request of the earlier application. It is determined whether the claimed invention of the later application is within the scope of matters disclosed in the description etc. originally attached to the request of the earlier application or not, depending on the examples of new matters.

One of the provisions of the Uruguay Round Agreements Act (URAA - effective date of June 8, 1995) is the establishment of a domestic priority system in U.S. patent law. The Act provides a mechanism to enable domestic applicants to quickly and inexpensively file provisional applications. See 35 U.S.C. 119(e). The filing date of a provisional application is the date on which a specification complying with 35 U.S.C. 112, first paragraph and any drawings required by 35 U.S.C. 113 are filed. No claims are required and no oath or declaration is required. A provisional application is not examined and will automatically be abandoned 12 months from its filing date and will not be subject to revival thereafter. A provisional application is a regular national filing that starts the Paris Convention priority year. A nonprovisional application may be filed within 12 months from the filing date of the provisional application claiming the benefit of the filing date of the provisional application under 35 U.S.C. 119(e). The written description and drawings (if any) of the provisional application must adequately support and enable the subject matter of the claim in the later-filed nonprovisional application. If a claim in the nonprovisional application is not adequately supported by the written description and drawings (if any) of the provisional application, that claim in the nonprovisional application is NOT entitled to the benefit of the filing date of the provisional application. See MPEP 201.11, subsection I.A.

(7) Determination of invention based on disclosure - Does the applicant or the examiner make the determination of what invention has been disclosed in the description?

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

Since it is the applicant who determines for what invention to seek a patent, this Article sets forth that the applicant shall state in the claim all matters the applicant himself/herself deems necessary to define the invention for which a patent is sought.

EPO comments that an independent claim should specify all of the essential features needed to define the invention. It is the responsibility of the applicant to ensure that he supplies, on filing his application, a sufficient disclosure, i.e. one that supports the invention as claimed in all of the claims. Any inconsistency between the description and the claims should be avoided.

The applicant makes the determination of the invention, but the examiner may influence, by his objections, this determination. For example, if the description leads the reader to believe that a feature, not contained in an independent claim, is essential to the performance of the invention, then this feature must be brought into that claim or shown not to be essential. In addition, if documents have been found which are so relevant as to render the presentation of the invention no longer appropriate the examiner may indicate to the applicant that the problem to be solved is not correctly define and require him to amend the description and the claims accordingly.

The examiner decides whether or not the claims as suggested satisfy the various conditions of patentability. In so doing, the examiner may suggest amended claims in order to overcome the objection made. The EPO would permit the examiner to determine what the invention is, from a reading of the disclosure. He would make the determination of whether all essential features are present in the claims. The term "essential feature(s)" does not mean "all those features described" nor does it necessarily mean the specific example of a particular feature. The feature of any claim may be set out as broadly as is justifiable from the disclosure without bringing it into conflict with the prior art. Nevertheless, all the essential features need to be present in an independent claim.

The examiner may raise an objection that a claim lacks an essential feature. It should be emphasized here that applicants can (and do) argue that an examiner is mistaken in his or her view that a certain feature is essential. However, the EPC is interpreted as allowing a final rejection if examiner and applicant maintain

opposed views in this respect. The ground of final rejection would then be lack of the clarity.

According to USPTO practice, the invention at issue in a given patent application is that defined by the scope of the claims. The scope of this invention is not necessarily measured by the scope of the disclosure. Thus, the claimed invention may be broader or narrower than a specifically disclosed embodiment. By virtue of the fact that it is the applicant who presents claims to be examined, it can be said that it is the applicant who, at the least, begins the process of determining the invention for the purpose of patent protection.

While the USPTO examiner may apply prior art in rejecting claims for lack of novelty or inventive step or may reject claims because they are broader than the enabling disclosure, often leading to a narrowing of the scope of the, claims, it must be noted that these rejections may be successfully rebutted by the applicant without narrowing the claims.

The USPTO examiner may not conclude, from a review of the disclosure, that certain features of an invention are "indispensable" or "essential" and then require that these features be added to the claims.

The only claim requirement in US law is found in 35 U.S.C. §112, second paragraph; it is generally referred to as the "definiteness" requirement. This "definiteness" requirement is similar to the clarity requirements in Article 83 EPC and implicitly, in Article 36 (6)(ii) of the Japanese Patent Act. The US disclosure requirements that are set forth in 35 U.S.C. § 112, first paragraph, parallel, with the exception of the US best mode requirement, similar requirements in Article 83 EPC and Article 36 (4)(i) of the Japanese Patent Act.

Accordingly, it can be seen that the disclosure and claiming requirements of US Patent Law do not include requirements that parallel the "essential technical feature" requirements of and EPO. However, the USPTO examiner may reject claims because they are broader than the enabling disclosure, often leading to a narrowing of the scope of the claims.

(8) Prohibited matters or inadmissible elements (e.g. superfluous elements, reference to the spirit or essence of the invention, violation of public order, morality or public health, trademarks)

– Superfluous elements

JPO states that if a claim or claims include the words such as "if desired", "if necessary", there are some cases where the description of the claims is be clear.

EPO states that superfluous elements are prohibited in the European patent application and that matter may also become superfluous in the course of the examination.

USPTO does not comment on this point.

– Reference to the spirit or essence of the invention

In EPO, general statements in the description which imply that the extent of protection may be expanded in some vague and not precisely defined way are objected to under Article 84 EPC as this obviously obscures the scope of the claims.

In USPTO, an applicant is not required to comprehend the underlying scientific principle or theory upon which his/her invention rests and, therefore, need not include the same in an application.

JPO does not comment on this point.

– Violation of public order, morality or public health

JPO and EPO prohibit such matter although the EPC does not make a specific reference to public health. JPO states that such matter is not published in the Patent Gazette. EPO states that such matter must be deleted before the publication of the application.

On the other hand, there is no provision with respect to such matter in US Patent Law. USPTO comments that a rejection under 35 U.S.C. 101 for lack of utility should NOT be based on grounds that the invention is frivolous, fraudulent or against public policy. See Juicy Whip Inc. v. Orange Bang Inc., 51 USPQ2d 1700 (Fed. Cir. 1999) ("[Y]ears ago courts invalidated patents on gambling devices on the ground that they were immoral..., but that is no longer the law...Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted...we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public."). See MPEP 706.03(a).

– Trademark

All three Offices coincide in that the use of trademarks is permitted provided certain conditions are satisfied.

JPO states that where a claim includes a statement to define a product by means of a trademark, such a statement is deemed as making the claimed invention unclear unless it is clear to a person skilled in the art that the product had been maintained a certain quality, composition and structure, etc., at least for a certain period of time as of the filing.

EPO states that in the claims, use of trademarks is not allowed unless their use is unavoidable; they may be allowed exceptionally if they are generally recognized as having a precise meaning.

USPTO states that names used in trade are permissible in applications if their meanings are established by an accompanying definition or their meanings are well known and satisfactorily defined in the literature in the U.S.

– Others

In EPO and USPTO, derogatory remarks concerning the inventions of others are prohibited.

In USPTO, U.S. patents are not granted for any invention or discovery which is useful solely in the utilization of atomic energy. All applications are also screened for subject matter, the disclosure of which might detrimentally impact the national security. If disclosure is determined to be detrimental to the national security, the Commissioner is notified and a Secrecy Order is issued to withhold the grant of a patent for such period as the national interest requires.