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Madam,
Sir,

Proposed Modifications to Chapter 10 of the International Search and Preliminary Examination Guidelines

This Circular is addressed to your Office in its capacity as an International Searching Authority, International Preliminary Examining Authority and/or designated or elected Office under the Patent Cooperation Treaty (PCT). It is also being sent to certain non-governmental organizations representing users of the PCT System.

The Quality Subgroup of the Meeting of International Authorities under the PCT, at its ninth informal meeting in February 2019, discussed unity of invention, including proposed modifications to Chapter 10 of the International Search and Preliminary Examination Guidelines "the Guidelines". These discussions are summarized in paragraphs 46 to 51 of the Summary by the Chair, set out in Annex II to document PCT/MIA/26/13; paragraph 51 outlines the recommendations of the Subgroup, as follows:

> "51. The Subgroup invited Authorities concerned to present specific proposals to address the outstanding comments via the electronic forum within a period of around two weeks, with agreement shortly thereafter. If possible, further proposals might also be made to cover some of the outcomes of the work undertaken by the PHEP. The International Bureau should prepare a PCT Circular on the basis of the agreed text for consultation with designated Offices and user groups. Any outstanding matter would be further considered for discussion in the Subgroup electronic forum with a view to concluding this review exercise at the Subgroup meeting next year.

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In response to the above recommendation of the Subgroup, discussions on proposed modifications to the Guidelines took place on the electronic forum after the ninth informal meeting. Following these discussions, this Circular proposes, for consultation, modifications to Chapter 10 of the Guidelines that have support from the Subgroup. The proposed
./. modifications are set out in the Annex. In the meantime, discussions will continue on the electronic forum on potential further modifications to Chapter 10 that do not form part of the proposals in the Annex with a view to reaching consensus on any further modifications as soon as possible.

The proposed modifications classify the existing examples in paragraphs 10.21 to 10.59 of the Guidelines into seven different categories (a) to (g) as listed in the proposed paragraph 10.20. Where applicable for the category, the proposed modifications list all the examples where unity of invention exists within the category, followed by the examples with no unity of invention. In addition to re-ordering the examples in the present Chapter 10, the proposed modifications include new examples to provide additional guidance for complex claims, and the situations of lack of unity in dependent claims and in a single independent claim.

You are invited to provide comments to the International Bureau on the proposed modifications. Replies should be sent by November 15, 2019, preferably by e-mail to the PCT Business Development Division: pct.bdd@wipo.int.

Yours sincerely,

John Sandage
Deputy Director General

Enclosure: Annex – Proposed Modifications to Chapter 10 of the International Search and Preliminary Examination Guidelines

Chapter 10
Unity of Invention

Determination of Unity of Invention

Article 17(3)(a); Rule 13; Section 206

10.01 An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Rule 13.2; AI Annex B, paragraph (b)

10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

Rule 13.2

10.03 Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known or obvious (see Chapter 13 for guidance on obviousness), there may be lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

10.04 Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the applicant.

10.05 From the preceding paragraphs it is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority. However, the Authority should not raise objection of lack of unity of invention merely because the inventions claimed are classified in separate classification

groups or merely for the purpose of restricting the international search to certain classification groups.

AI Annex B, paragraph (c)

10.06 Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, in a situation like the plug and socket example in paragraph 5.19, a claim to the one part referring to the other cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim.

10.07 If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. For example, suppose claim 1 claims a turbine rotor blade shaped in a specified manner, while claim 2 is for a "turbine rotor blade as claimed in claim 1" and produced from alloy Z. Then no objection under Rule 13 arises either because alloy Z was new and its composition was not obvious and thus the alloy itself already contains the essential features of an independent possibly later patentable invention, or because, although alloy Z was not new, its application in respect of turbine rotor blades was not obvious, and thus represents an independent invention in conjunction with turbine rotor blades. As another example, suppose that the main claim defines a process for the preparation of a product A starting from a product B and the second claim reads: "Process according to claim 1 characterized by producing B by a reaction using the product C." In this case, too, no objection arises under Rule 13.1, whether or not the process for preparation of B from C is novel and inventive, since claim 2 contains all the features of claim 1. The subject matter of claim 2 therefore falls within claim 1. Equally, no problem arises in the case of a genus/ species situation where the genus claim avoids the prior art and satisfies the requirement of unity of invention. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and satisfies the requirement of unity of invention and the combination claim includes all the features of the subcombination.

10.08 If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation. This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

10.09 Alternative forms of an invention may be claimed either in a plurality of independent claims, or in a single claim (but see paragraph 5.18). In the latter case, the presence of the independent alternatives may not be immediately apparent. In either case, however, the same criteria are applied in deciding whether or not there is unity of invention, and lack of unity of invention may then also exist within a single claim. Where the claim contains distinct embodiments that are not linked by a single general inventive concept, the

objection as to lack of unity of invention is raised. Rule 13.3 does not prevent an Authority from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority.

10.10 Objection of lack of unity of invention does not normally arise if the combination of a number of individual elements is claimed in a single claim (as opposed to distinct embodiments as discussed in the paragraph immediately above), even if these elements seem unrelated when considered individually (see paragraph 15.31).

Illustrations of Particular Situations

AI Annex B, paragraph (d)

10.11 There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

(i) combinations of different categories of claims;

(ii) so-called "Markush practice;" and

(iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2. Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

Combinations of Different Categories of Claims

AI Annex B, paragraph (e)

10.12 The method for determining unity of invention under Rule 13 is construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product (see paragraph 10.21 - Example 1), or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process (see paragraph 10.38 - Example 18), or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process.

A process is specially adapted for the manufacture of a product if it inherently results in the product and an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

10.13 Thus, a process is considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

10.14 Also an apparatus or means is considered "specifically designed for carrying out" a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

10.15 More extensive combinations than those set forth in paragraph 10.12 should be looked at carefully to ensure that the requirements of both Rule 13 (unity of invention) and Article 6 (conciseness of claims) are satisfied. (See paragraph 5.42 regarding conciseness of claims.) In particular, while a single set of independent claims according to one of the subparagraphs of paragraph 10.12 is always permissible, it does not require the International Authority to accept a plurality of such sets which could arise by combining the provisions of Rule 13.3 (which provides that the determination of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim), with the provisions set out in paragraph 10.12 (thus resulting in a set under paragraph 10.12 based on each of a number of independent claims in the same category under Rule 13.3 (see paragraphs 5.12 to 5.14)). The proliferation of claims arising from a combined effect of this kind should be accepted only exceptionally. For example, independent claims are permissible for two related articles such as a transmitter and receiver; however, it does not follow that, under paragraph 10.12, an applicant may include also, in the one international application, four additional independent claims: two for a process for the manufacture of the transmitter and the receiver, respectively, and two for use of the transmitter and receiver, respectively.

10.16 A single general inventive concept must link the claims in the various categories and in this connection the wording of paragraph 10.12 should be carefully noted. The link between product and process in subparagraph (i) is that the latter must be "specially adapted for the manufacture of" the former. Similarly, in paragraph 10.12, subparagraph (ii), the apparatus or means claimed must be "specifically designed for" carrying out the process. Likewise, in subparagraph (iii), the process must be "specially adapted for the manufacture of)" the product and the apparatus must be "specifically designed for" carrying out the process. In combinations (i) and (iii), the emphasis is on, and the essence of the invention should primarily reside in, the product, whereas in combination (ii) the emphasis is on, and the invention should primarily reside in, the process. ~~(See Examples below.)~~

"Markush Practice"

AI Annex B, paragraph (f)

10.17 Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.

(a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(b) In paragraph (a)(B)(1), above, the words “significant structural element is shared by all of the alternatives” refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together. (See paragraphs 10.46 and 10.47 – Examples 26 and 27).

(c) In paragraph (a)(B)(2), above, the words “recognized class of chemical compounds” mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved. (See paragraph 10.53 - Example 33).

(d) The fact that the alternatives of a Markush grouping can be differently classified is not, taken alone, considered to be justification for a finding of a lack of unity of invention.

(e) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity will be raised.

~~(See Examples below.)~~

Intermediate and Final Products

AI Annex B, paragraph (g)

10.18 Rule 13.2 also governs the situation involving intermediate and final products.

(a) The term “intermediate” is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

(b) Unity of invention is considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural element, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element. (See paragraphs 10.28 and 10.29 – Examples 8 and 9).

(c) Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known, for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there must be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final

product or incorporates an essential element into the final product. (See paragraphs 10.32 and 10.33 – Examples 12 and 13).

(d) It is possible in a single international application to accept different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.

(e) The intermediate and final products must not be separated, in the process leading from one to the other, by an intermediate that is not new.

(f) If the same international application claims different intermediates for different structural parts of the final product, unity is not regarded as being present between the intermediates.

(g) If the intermediate and final products are families of compounds, each intermediate compound must correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

AI Annex B, paragraph (h)

10.19 As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities should not affect the decision on unity of invention.

Examples Concerning Unity of Invention

10.20 The application of the principles of unity of invention is illustrated by the following examples for guidance in particular cases.

Determining special technical features is addressed in paragraphs 10.01 to 10.10, above. It is recognized that Authorities may differ in determining which features are special technical features on a case by case basis based on how the Authority determines whether any shared technical features make a contribution over the prior art. Except as otherwise noted, the following examples proceed on the basis that the shared technical feature is, as determined by the Authority, a special technical feature.

Different Aspects of the Invention Claimed (Method, Apparatus, Product etc.) ~~*Claims in Different Categories*~~

Unity of Invention Exists - Examples 1 to 14

10.21 *Example 1*

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The (method of) use of substance X as an insecticide.

Unity exists *a priori* between claims 1, 2 and 3 because the~~. The~~ special technical feature common to all the claims is substance X. ~~However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.~~ However, if substance X does not define a contribution over the prior art, there would not be a special technical feature common to all the claims. Accordingly, unity may be lacking (see paragraph 10.20).

10.22 *Example ~~4~~2*

Claim 1: Use of a family of compounds X as insecticides.

Claim 2: Compound X_1 belonging to the family of compounds X.

~~Provided X_1 has the insecticidal activity and the special technical feature in claim 1 is the insecticidal use, unity is present.~~ Unity exists between claims 1 and 2. The special technical feature is the use of the family of compounds X as an insecticide, provided X_1 has the insecticidal property.

10.23 *Example ~~7~~3*

Claim 1: A high corrosion resistant and high strength ferritic stainless steel strip consisting essentially of, in percent by weight: Ni=2.0-5.0; Cr=15-19; Mo=1-2; and the balance Fe, having a thickness of between 0.5 and 2.0 mm and a 0.2% yield strength in excess of 50 kg/mm squared.

Claim 2: A method of producing a high corrosion resistant and high strength ferritic stainless steel strip consisting essentially of, in percent by weight: Ni=2.0-5.0; Cr=15-19; Mo=1-2; and the balance Fe, comprising the steps of:

(a) hot rolling to a thickness between 2.0 and 5.0 mm;

(b) annealing the hot rolled strip at 800-1000°C under substantially no oxidizing conditions;

(c) cold rolling the strip to a thickness of between 0.5 and 2.0 mm; and

(d) final annealing the cold rolled strip at between 1120 and 1200°C for a period of 2-5 minutes.

Unity exists between product claim 1 and process claim 2. The special technical feature in the product claim is the 0.2% yield strength in excess of 50 kg/mm squared. The process steps in claim 2 inherently produce a ferritic stainless steel strip with a 0.2% yield strength in excess of 50 kg/mm squared. Even if this feature is not apparent from the wording of claim 2, it is clearly disclosed in the description. Therefore ~~said~~ the process steps are the special technical feature which correspond to the limitation in the product claim directed to the same ferritic stainless steel with the claimed strength characteristics.

10.24 *Example ~~13~~4*

Claim 1: Filament A for a lamp.

Claim 2: Lamp B having filament A.

Claim 3: Searchlight provided with lamp B having filament A and a swivel arrangement C.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is the filament A.

10.25 *Example ~~14~~5*

Claim 1: A marking device for marking animals, comprising a disc-shaped element with a stem extending normally therefrom, the tip of which is designed to be driven through the skin of the animal to be marked, and a securing disk element to be fastened to the protruding tip of the stem on the other side of skin.

Claim 2: An apparatus for applying the marking device of claim 1, constructed as a pneumatically actuated gun for driving the stem of the disc-shaped element through the skin, and provided with a supporting surface adapted for taking up a securing disc element, to be placed at the other side of the body portion in question of the animal to be marked.

The special technical feature in claim 1 is the marking device having a disc-shaped element with a stem and a securing disc element to be fastened to the tip of the stem. The corresponding special technical feature in claim 2 is the pneumatically actuated gun for driving the marking device and having a supporting surface for the securing disc element. Unity exists between claims 1 and 2.

10.26 *Example ~~15~~6*

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

10.27 *Example ~~16~~7*

Claim 1: An insecticide composition comprising compound A (consisting of a_1, a_2...) and a carrier.

Claim 2: Compound a_1.

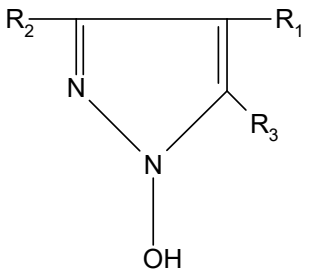
All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance.

There is nevertheless still unity between the subject matter of claims 1 and 2 provided a_1 has the insecticidal activity that is also the special technical feature for compound A in claim 1.

~~*Claims in the Same Category*~~

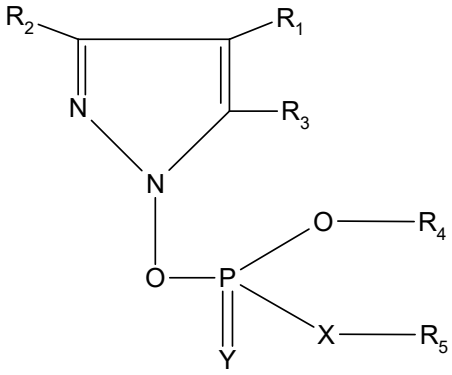
10.28 *Example ~~26~~8 (Intermediate/Final Product)*

Claim 1:



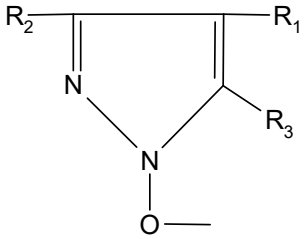
(intermediate)

Claim 2:



(final product)

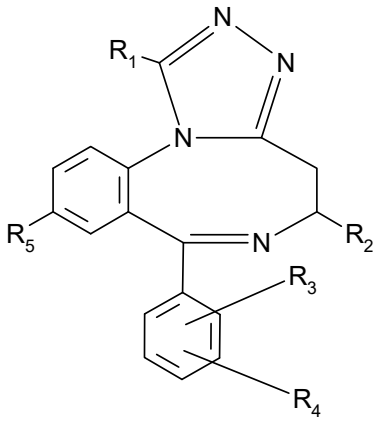
The chemical structures of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:



Therefore, unity exists between claims 1 and 2.

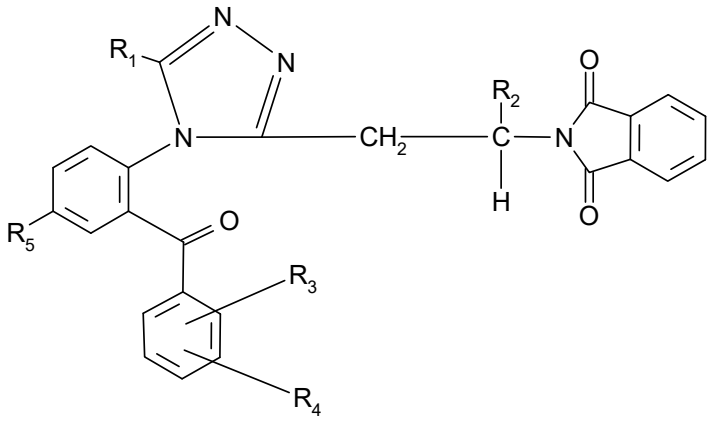
10.29 *Example ~~27~~9 (Intermediate/Final Product)*

Claim 1:



(I)

Claim 2:



(II)

(II) is described as an intermediate to make (I). The closure mechanism is one well known in the art. Though the basic structures of compound (I) (final product) and compound (II) (intermediate) differ considerably, compound (II) is an open ring precursor to compound (I). Both compounds share a common essential structural element that is the linkage comprising the two phenyl rings and the triazole ring. The chemical structures of the two compounds are therefore considered to be technically closely interrelated.

The example therefore satisfies the requirement for unity of invention.

10.30 *Example ~~28~~10 (Intermediate/Final Product)*

Claim 1: Amorphous polymer A (intermediate).

Claim 2: Crystalline polymer A (final product).

In this example a film of the amorphous polymer A is stretched to make it crystalline.

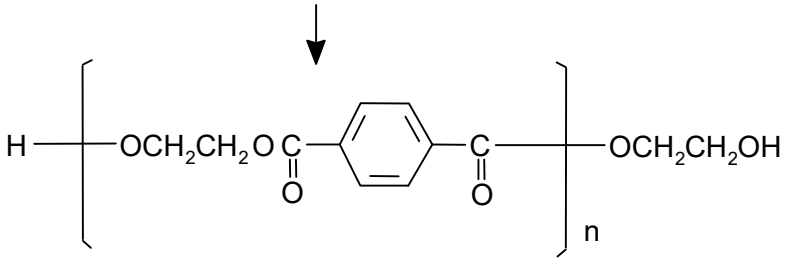
Here unity exists because there is an intermediate final product relation in that amorphous polymer A is used as a starting product to prepare crystalline polymer A.

For purposes of further illustration, assume that the polymer A in this example is polyisoprene. Here the intermediate, amorphous polyisoprene, and the final product, crystalline polyisoprene, have the same chemical structure.

10.31 *Example ~~29~~11 (Intermediate/Final Product)*

Claim 1: Polymeric compound useful as fiber material identified by the following general formula:

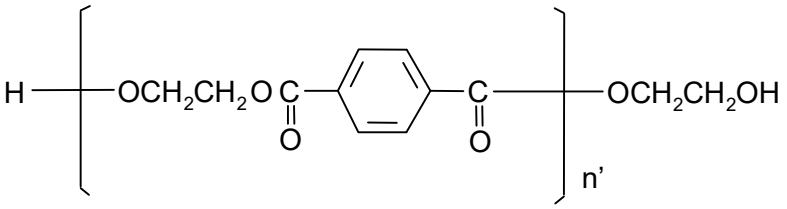
[repeating unit (X)]



(I)

Claim 2: Compound identified by the following general formula:

(useful as intermediate for polymeric compound I)



(II)

(primary condensation product)

The two inventions are in an intermediate and final product relationship.

Substance (II) is a raw material for substance (I).

Meanwhile, both compounds share an essential structural element (repeating unit (X)) and are technically closely interrelated. The intermediate and final products therefore satisfy the requirements for unity.

10.32 *Example ~~30~~12 (Intermediate/Final Product)*

Claim 1: Novel compound having structure A (intermediate).

Claim 2: Product prepared by reacting A with a substance X (final product).

(see below for further details)

10.33 *Example ~~31~~13 (Intermediate/Final Product)*

Claim 1: Reaction product of A and B (intermediate).

Claim 2: Product prepared by reacting the reaction product of A and B with substances X and Y (final product).

In examples ~~30~~12 and ~~31~~13 the chemical structure(s) of the intermediate and/or the final product is not known. In ~~30~~12 the structure of the product of claim 2 (the final product) is not known. In ~~31~~13 the structures of the products of claim 1 (the intermediate) and claim 2 (the final product) are unknown.

Unity exists if there is evidence that would lead one to conclude that the characteristic of the final product which is the inventive feature in the case is due to the intermediate. For example, the purpose for using the intermediates in Examples ~~30~~12 and ~~31~~13 is to modify certain properties of the final product. The evidence may be in the form of test data in the

specification showing the effect of the intermediate on the final product. If no such evidence exists then there is no unity on the basis of an intermediate-final product relationship.

10.34 *Example ~~39~~14(A)~~:~~ (Protein and its Encoding DNA)*

Claim 1: Isolated protein X having SEQ ID NO: 1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO: 1.

There is no prior art and so SEQ ID NO:1 and SEQ ID NO:2 are both novel and inventive.

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Please note that although it is generally accepted that DNA and the corresponding encoded protein share unity of invention *a priori*, given the special relationship between these two classes of molecules (i.e., DNA encodes protein following the well-known genetic code), some Authorities may hold that exceptions exist as noted below.

Further, because ~~Because~~ protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature *a posteriori*.

Example 14(B)

If an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X, some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity *a priori*. Examples of such ~~a~~ claims ~~follow~~ are:

Claim 3: Isolated DNA molecule encoding protein X, or a DNA fragment thereof.

Claim 4: Isolated DNA molecule having SEQ ID NO: 2, or DNA molecules which hybridize to the complement of SEQ ID NO: 2 under stringent conditions.

Some Authorities may consider claim 3 to lack unity on the basis that the DNA fragment and the hybridizing DNA molecules are not limited to encoding protein X. Other Authorities may interpret "DNA fragment thereof" or hybridizing molecules as being derived from the DNA molecule and representative of the same general inventive concept, and therefore consider unity to be present.

DNA molecules which hybridize to the complement of SEQ ID NO:2 under stringent conditions share significant identity to SEQ ID NO:2. Therefore, some Authorities may consider claim 4 to be directed to the same general inventive concept, and therefore consider unity to be present.

If prior art existed teaching either protein X or the DNA encoding protein X, some Authorities might find that the same or corresponding technical feature did not make a contribution over the prior art, that is, was not a special technical feature, and therefore unity was lacking (*a posteriori*).

Example 14(C)

In addition, if it was thought that a finding of unity of invention *a priori* for a protein (or a class of proteins) and a nucleic acid (or a class of nucleic acids) would conflict with other guidance, such as the Markush test, some Authorities might find that the claims do not share the same or corresponding special technical feature and therefore lack unity of invention *a priori* or *a posteriori* depending on the facts.

Examples of such claims are:

Claim 5: An isolated protein with function X.

Claim 6: Isolated DNA molecules encoding a protein with function X selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID No: 3.

If SEQ ID Nos: 1 to 3 lack unity *a priori* under the "Markush test" (e.g., fail parts (B)(1) and (B)(2) of the Markush test in paragraph 10.17) because the DNA SEQ ID NOs: 1 to 3 encode structurally distinct proteins from different families that are not structurally/evolutionarily related (such as, for instance, the subtilisin-like and chymotrypsin-like serine proteases that are known to coincidentally possess the same serine protease function even though they have completely different structures and belong to evolutionarily distinct families), some Authorities might find that unity of invention does not exist a priori between the isolated DNA SEQ ID NOs: 1-3 and corresponding encoding proteins with function X.

No Unity of Invention (*a priori*) - Examples 15 to 16

10.35 *Example ~~5~~15*

Claim 1: A process for treating textiles comprising spraying the material with a particular coating composition under special conditions (for example, as to temperature, irradiation).

Claim 2: A textile material coated according to the process of claim 1.

Claim 3: A spraying machine for use in the process of claim 1 and characterized by a new nozzle arrangement providing a better distribution of the composition being sprayed.

The process according to claim 1 imparts unexpected properties to the product of claim 2. The special technical feature in claim 1 is the use of special process conditions corresponding to what is made necessary by the choice of the particular coating. Unity exists between claims 1 and 2. The spraying machine in claim 3 does not correspond to the above identified special technical feature. Unity does not exist between claim 3 and claims 1 and 2.

10.36 *Example ~~6~~16*

Claim 1: A fuel burner with tangential fuel inlets into a mixing chamber.

Claim 2: A process for making a fuel burner including the step of forming tangential fuel inlets into a mixing chamber.

Claim 3: A process for making a fuel burner including casting step A.

Claim 4: An apparatus for carrying out a process for making a fuel burner including feature X resulting in the formation of tangential fuel inlets.

Claim 5: An apparatus for carrying out a process for making a fuel burner including a protective housing B.

Claim 6: A process of manufacturing carbon black including the step of tangentially introducing fuel into a mixing chamber of a fuel burner.

Unity exists between claims 1, 2, 4, and 6. The special technical feature common to all the claims is the tangential fuel inlets. Claims 3 and 5 lack unity with claims 1, 2, 4, and 6 since claims 3 and 5 do not include the same or corresponding special technical feature as set forth in claims 1, 2, 4, and 6. Claims 3 and 5 would also lack unity with one another.

Claims have Overlapping Features but Progressively Add New Features

Unity of Invention Exists – Example 17

10.37 *Example ~~12~~17*

Claim 1: A display with features A + B.

Claim 2: A display according to claim 1 with additional feature C.

Claim 3: A display with features A + B with additional feature D.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is features A + B.

~~*Markush Practice*~~

No Unity of Invention (*a priori*) – Examples 18 to 20

10.38 *Example ~~2~~18*

Claim 1: A process of manufacture comprising steps A and B.

Claim 2: Apparatus specifically designed for carrying out step A.

Claim 3: Apparatus specifically designed for carrying out step B.

Unity exists between claims 1 and 2 or between claims 1 and 3. There is no unity between claims 2 and 3 since there exists no common special technical feature between the two claims.

10.39 *Example ~~3~~19*

Claim 1: A process for painting an article in which the paint contains a new rust inhibiting substance X including the steps of atomizing the paint using compressed air, electrostatically charging the atomized paint using a novel electrode arrangement A and directing the paint to the article.

Claim 2: A paint containing substance X.

Claim 3: An apparatus including electrode arrangement A.

Unity exists between claims 1 and 2 where the common special technical feature is the paint containing substance X or between claims 1 and 3 where the common special technical feature is the electrode arrangement A. However, unity is lacking between claims 2 and 3 since there exists no common special technical feature between them.

10.40 *Example 20*

Claim 1: Carbon steel comprising 0.10-0.40% manganese.

Claim 2: Carbon steel comprising 0.60-1.65% manganese.

Claim 3: Carbon steel comprising 0.50-0.90% manganese.

The specification notes that –

- *Carbon steel comprising 0.10-0.40% manganese results in reduced oxidation at high temperatures.*
- *Carbon steel comprising 0.60-1.65% manganese results in improved electrical conductivity.*
- *Carbon steel comprising 0.50-0.90% manganese results in improved strength while surprisingly drastically improving ductility.*

It is common general knowledge that carbon steel contains manganese. Claims 1 and 2 and claims 1 and 3 lack unity *a priori* but unity of invention exists between claims 2 and 3. However, if prior art existed teaching or suggesting any part of the overlapping range within 0.60-0.90% manganese in carbon steel resulting in improved electrical conductivity and/or improved strength while surprisingly drastically improving ductility, then unity would not exist *a posteriori* between claims 2 and 3.

Complementary Forms of the Invention (e.g. Receiver and Transmitter)

Unity of Invention Exists – Examples 21 and 22

10.41 *Example ~~8~~21 (Claims in the Same Category)*

Claim 1: Plug characterized by feature A.

Claim 2: Socket characterized by corresponding feature A.

Feature A is a special technical feature that is included in both claims 1 and 2 and therefore unity is present.

10.42 *Example ~~9~~22 (Claims in the Same Category)*

Claim 1: Transmitter provided with time axis expander for video signals.

Claim 2: Receiver provided with time axis compressor for video signals received.

Claim 3: Transmission equipment for video signals comprising a transmitter provided with time axis expander for video signals and a receiver provided with time axis compressor for video signals received.

The special technical features are, in claim 1 the time axis expander, and in claim 2 the time axis compressor, which are corresponding technical features. Unity exists between claims 1 and 2. Claim 3 includes both special technical features and has unity with claims 1 and 2. The requirement for unity would still be met in the absence of the combination claim (claim 3).

~~*Example 10*~~

~~*Claim 1: Conveyor belt with feature A.*~~

~~*Claim 2: Conveyor belt with feature B.*~~

~~*Claim 3: Conveyor belt with features A + B.*~~

~~*Feature A is a special technical feature and feature B is another unrelated special technical feature.*~~

~~Unity exists between claims 1 and 3 or between claims 2 and 3, but not between claims 1 and 2.~~

No Unity of Invention (*a priori*) – Examples 23

10.43 *Example ~~38~~23~~:~~ (Method of Screening and Compounds Identified by the Method)*

Claim 1: A method to identify compounds that are antagonists of receptor R comprising the steps of contacting cells expressing on their outer membrane receptor R with its natural ligand; observing the binding of the ligand; contacting said cells bound to said ligand with a candidate compound selected from a library of compounds; and observing any change in the binding of the ligand.

Claim 2: Compound X, having formula 1.

Claim 3: Compound Y, having formula 2.

Claim 4: Compound Z, having formula 3.

Receptor R and its natural ligand are proposed as a drug target. Compounds that antagonize receptor R are proposed to have physiological effects that may be useful in therapeutic treatment. The aim is to identify lead compounds as a basis for further screening and testing of combinatorial libraries. A library is described as providing many possible structurally different compounds. Examples show that the method of claim 1 can be used to identify compounds affecting the physiological effect of binding of the natural ligand to the receptor. Only compounds X, Y and Z were shown to have such effects, but they do not appear to share a significant structural element. The description is silent with regard to both the relationship between the structure and activity of the claimed compounds and the relationship between the structure of receptor R and the structure of the compounds.

Receptor R, its biological function, and its natural ligand are known in the prior art. No compounds that function as antagonists of receptor R are known.

The technical feature of method claim 1 resides in the step of observing the effect of the candidate compounds on ligand binding in a screening assay. Neither the same nor a corresponding special technical feature is present in any of compounds X, Y, or Z. No manufacturing relationship exists between the screening method and the claimed compounds. Further, the screening method is not a method of using claimed compounds X, Y, and Z. In the absence of any teaching as to the structure required for a compound to act as a receptor R antagonist, there is no single general concept that links the method to the claimed compounds. Thus, unity of invention is lacking (*a priori*).

Compounds X, Y, and Z would be regarded as having the same or corresponding technical feature if they had a common property or activity, and shared a significant structural element that is essential to the common property or activity. While compounds X, Y, and Z do share the common property of antagonizing receptor R, there is no teaching as to a shared significant structural element, and hence, there is no disclosure of the same or corresponding technical feature.

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)

Invention 2: Compound X (claim 2)

Invention 3: Compound Y (claim 3)

Invention 4: Compound Z (claim 4)

Alternative Forms of an Aspect of the Invention (Varying Solutions to the Same Problem)

Unity of Invention Exists – Examples 24 to 30

10.44 *Example ~~17~~24*

Claim 1: A chair with a lifting mechanism.

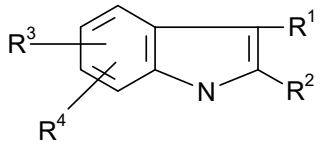
Claim 2: A chair with a mechanical screw lifting mechanism.

Claim 3: A chair with a hydraulic lifting mechanism.

Unity exists *a priori* between claims 1, 2 and ~~-~~3~~.~~ because the ~~The~~ special technical feature common to all the claims is a chair with a ~~the~~ lifting mechanism. However, if a~~ny~~ chair with a lifting mechanism is known in the art, ~~unity would be lacking because~~ there would not be a special technical feature common to all the claims and unity of invention would be lacking.

10.45 *Example ~~18~~25(A)~~:~~ (Common Structure)*

Claim 1: A compound of the formula:

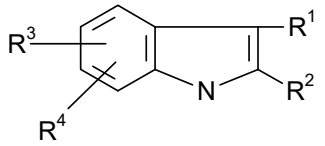


wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R^2-$R^4$are hydroxyl, methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case, the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present. This is consistent with Markush practice wherein a special technical feature is provided by a commonly shared structure which constitutes a structurally distinct portion in view of the prior art and the common structure is essential to the common property or activity (see paragraph 10.17).

Example 25(B) (Common Structure including a proviso in claim 1)

Claim 1: A compound of the formula:



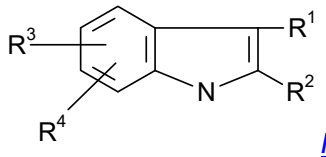
wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinly, alkylthio, alkoxy, and methyl; R^2-R^4 are hydroxyl, methyl, benzyl, or phenyl with the proviso that R^2 and R^3 cannot both be methyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case, the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present *a priori*. However, prior art that shows compounds having the same use and having this shared core structure could be used to show that this claim lacks unity of invention *a posteriori*. This prior art could even include prior art where both R^2 and R^3 are methyl since

the prior art only needs to teach what is shared (i.e., the prior art does not need to anticipate/render obvious the claims).

Example 25(C) (Common Structure including a functional limitation in claim 1)

Claim 1: A compound of the formula (I) having the property of enhancing the capacity of the blood to absorb oxygen:



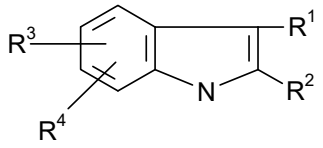
Formula (I)

wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinly, alkylthio, alkoxy, and methyl; R^2- R^4 are hydroxyl, methyl, benzyl, or phenyl.

In this case, the indolyl moiety is the significant structural element that is shared by all of the alternatives. Further, the specification and claims teach that all of the compounds of Formula (I) possess the claimed utility. Thus, unity is present *a priori*. Prior art teaching the shared structures possessing the claimed function could be used to show that this claim lacks unity of invention *a posteriori*. For some Authorities, even for prior art which teaches Formula (I) wherein R^1 is phenyl and R^2-R^4 are methyl, but is silent with regard to the claimed function, the lack of unity would be applicable since it would be regarded as inherently possessing the claimed function as evidenced by applicants' specification and/or other reference(s) which evidence this point, whether that evidence was published before or after Applicants' filing date since a compound and its properties are inseparable.

Example 25(D) (Common Structure including a functional alternative in claim 2)

Claim 1: A compound of the formula (I):



Formula (I)

wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinly, alkylthio, alkoxy, and methyl; R^2-R^4 are hydroxyl, methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

Claim 2: The compound of claim 1 where R^1 is pyridyl and R^2-R^4 are methyl.

In this case, the indolyl moiety is the significant structural element that is shared by all of the alternatives. Further, the specification and claims teach that all of the compounds of Formula (I) possess the claimed utility. Thus, unity is present *a priori*.

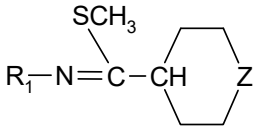
If unity of invention is lacking *a posteriori* then some Authorities would determine that the first named invention searched would be a compound of Formula (I) wherein R^1 is phenyl (not pyridyl) and R^2-R^4 are hydroxyl (not methyl) since those are the first named Markush members listed in claim 1 (see also Example 34). Note in such cases that the first claimed invention does not include any sub-genuses, but rather is limited to the first embodiment for each variable. However, the Authority/examiner may at their discretion and depending on the specific circumstances of the case include one or more sub-genuses within the first invention.

Alternatively, an Authority may determine that the first invention searched may comprise different groupings. In most cases this determination will be made based on a consideration of the circumstances of the case including the interdependence of the different groups, the specific examples given in the application and the prior art that has been identified. For example, in the above case it may be considered that the phenyl, pyridyl, thiazolyl and triazinyl groups share a common property in that they are aromatic rings. However, prior art disclosing compounds having the same activity and comprising an aromatic group such as pyrimidine in this position could be used to raise a lack of unity between each of these groups.

In a further alternative, some Authorities may determine that each type of the first substituent, here R^1, is as the special technical feature; in other words if the Formula (I) wherein R^1 is phenyl is known from the prior art, then the first invention is the Formula (I) wherein R^1 is pyridyl and R^2-R^4 are hydroxyl, methyl, benzyl or phenyl (i.e. all options for R^2-R^4); the second invention is the formula wherein R^1 is thiazolyl and R^2-R^4 are hydroxyl, methyl, benzyl or phenyl, and so on.

10.46 *Example ~~19~~26~~:~~ (Common Structure)*

Claim 1: A compound of the formula:



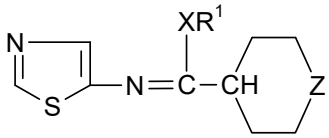
wherein R_1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; Z is selected from the group consisting of oxygen (O), sulfur (S), imino (NH), and methylene (-CH2-).

The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

In this particular case the iminothioether group -N=C-SCH3 linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.47 *Example ~~20~~27~~:~~ (Common Structure)*

Claim 1: A compound of the formula:

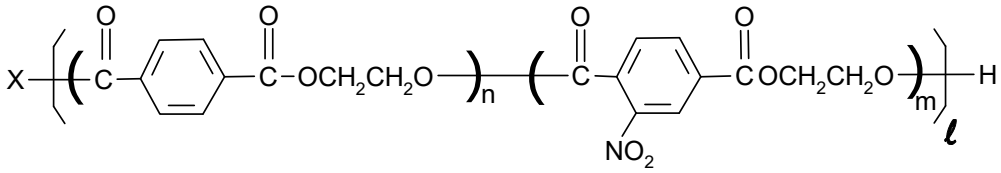


wherein R^1 is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).

The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mammalian tissue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents.

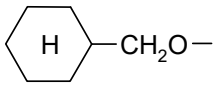
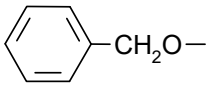
All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.48 *Example ~~21~~28~~:~~ (Common Structure)*



$1 \leq \ell \leq 10$

$200 \geq n + m \geq 100$

X:  *or* 

All of the above copolymers have in common a thermal degradation resistance property, due to the reduced number of free COOH radicals by esterification with X of the end COOH radicals which cause thermal degradation.

The chemical structures of the alternatives are considered to be technically closely interrelated to one another. A grouping in one claim is therefore allowed.

10.49 *Example ~~25~~29*

Claim 1: Catalyst for vapor phase oxidation of hydrocarbons, which consists of (X) or (X+a).

In this example (X) oxidizes RCH_3 into RCH_2OH and (X+a) oxidizes RCH_3 further into RCOOH.

Both catalysts share a common component and a common activity as oxidation catalyst for RCH_3. With (X+a) the oxidation is more complete and goes until the carboxylic acid is formed but the activity still remains the same.

A Markush grouping is acceptable in this case.

10.50 *Example ~~33~~30~~:~~ (Multiple Structurally and Functionally Related Polynucleotides)*

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The facts are the same as Example ~~32~~35 except that the claimed polynucleotides all share a significant structural element and their corresponding mRNAs are expressed only in the hepatocytes of patients with disease Y. The corresponding mRNAs are not expressed in the hepatocytes of healthy individuals.

There is no prior art available. The shared structural element had not been identified before, nor had any link been established between genes expressing mRNA containing that structural element and patients afflicted with disease Y.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description discloses that SEQ ID NOs:1-10 share a common property, that is, expression of an mRNA present only in patients afflicted with disease Y. Moreover, SEQ ID NOs: 1-10 share a significant structural element that is essential to the common property, i.e., a probe comprising the shared structural element can detect the mRNA of patients afflicted with disease Y. Since both of these requirements are met, the group of polynucleotide molecules claimed meets the requirement of unity of invention (*a priori*).

No Unity of Invention (*a priori*) – Examples 31 to 39

10.51 *Example ~~11~~31*

Claim 1: Control circuit A for a d.c. motor.

Claim 2: Control circuit B for a d.c. motor.

Claim 3: An apparatus including a d.c. motor with control circuit A.

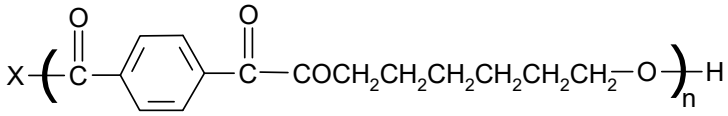
Claim 4: An apparatus including a d.c. motor with control circuit B.

Control circuit A is a special technical feature and control circuit B is another unrelated special technical feature.

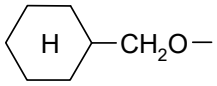
Unity exists between claims 1 and 3 or between claims 2 and 4, but not between claims 1 and 2 or 3 and 4.

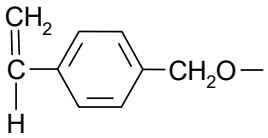
~~*Biotechnological Inventions*~~

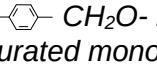
10.52 *Example ~~22~~32~~:~~ (Common Structure)*



$100 \geq n \geq 50$

X: 

or 

The compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with  *CH_2O- has a thermal degradation resistant property, due to the reduced number of free COOH radicals which cause thermal degradation. In contrast, the compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with a vinyl compound containing a*  *CH_2O- moiety serves as a raw material for a setting resin when mixed with unsaturated monomer and cured (addition reaction).*

All esters covered by the claim do not have a property or activity in common. For example, the product obtained through esterification with the "CH_2 = CH" vinyl compound does not have a thermal degradation resistant property. The grouping in a single application is not allowed.

10.53 *Example ~~23~~33~~:~~ (No Common Structure)*

Claim 1: A herbicidal composition consisting essentially of an effective amount of the mixture of A 2,4-D(2,4-dichloro-phenoxy acetic acid) and B a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil

(nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

The different components under B must be members of a recognized class of compounds. Consequently in the present case a unity objection would be raised because the members of B are not recognized as a class of compounds, but, in fact, represent a plurality of classes which may be identified as follows:

(a) inorganic salts:

copper sulfate

sodium chlorate

ammonium sulfamate

(b) organic salts and carboxylic acids:

sodium trichloroacetate

dichloropropionic acid

3-amino-2,5-dichlorobenzoic acid

(c) amides:

diphenamid

(d) nitriles:

ioxynil

(e) phenols:

dinoseb

(f) amines:

trifluralin

(g) heterocyclic:

simazine

10.54 *Example ~~24~~34*

Claim 1: A pharmaceutical compound of the formula:

A – B – C – D – E

wherein:

A is selected from C_1-C_{10} alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C_5-C_7 heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C_1-C_6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C_3-C_8 ether or thioether;

C is selected from C_5-C_8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C_4-C_8 carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the

various combinations. When determining the first invention, one approach is to take into account the content of the dependent claims ~~may be taken into account~~.

Another approach is for ~~Alternatively~~ the first ~~claimed~~ invention ~~may be considered to encompass~~ to be taken as the first mentioned structure for each variable, that is, A is C_1 alkyl, B is C_1 alkyl, C is a C_5 saturated heterocycle having one O heteroatom, D is C_1 alkyl, and E is a substituted phenyl. Dependent claims that are limited to this first invention may be considered as unified with the first invention and could all be searched without requiring an additional fee.

A further approach by some Authorities is to consider the first invention more broadly. For example, the first invention may be a compound wherein A is C_1-C_{10} alkyl, B is C_1-C_6 alkyl, C is a C_5-C_8 saturated heterocycle having one O heteroatom, D is C_1-C_6 alkyl, and E is a substituted or unsubstituted phenyl. In such cases, further combinations may be identified for which additional search fees are invited. For example, a second election could be a compound wherein A is alkenyl, B is alkenyl, C is a substituted or unsubstituted phenyl, D is C_4-C_8 carboxylic acid ester, and E is a naphthyl. In such cases, it may also be appropriate to consider the description and the examples in order to identify specific groups of compounds for which to invite additional search fees.

The grouping of claims containing many variables should be determined on a case by case basis consistent with the principles previously set out in these guidelines.

10.55 *Example ~~32~~35~~:~~ (Multiple Structurally and Functionally Unrelated Polynucleotides)*

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the claimed polynucleotides are 500 bp cDNAs obtained from a human liver cDNA library. The polynucleotides are structurally different and can be used as probes to obtain full-length DNAs, although there is no description of the function or biological activity of the corresponding proteins. Furthermore, the polynucleotides claimed are not homologous to each other.

There is no prior art available. A human liver cDNA library had not been established before.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity, as determined by the Authority (see paragraph 10.05). Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the polynucleotides SEQ ID NOs: 1-10 share a common property or activity. While each sequence may serve as a probe to isolate its own respective full length DNA, due to the lack of homology between SEQ ID NOs: 1-10, a probe derived from SEQ ID NO: 1 cannot be used to isolate SEQ ID NOs: 2-10, respectively.

Moreover, since the polynucleotides are not homologous to each other, they fail to share a common structure i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. Therefore, the 10 polynucleotide molecules do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments are derived from the same source (human liver) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure, as determined by the Authority. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention (*a priori*).

One possible grouping would be:

Inventions 1-10: Polynucleotides having SEQ ID NOs: 1-10.

10.56 *Example ~~34~~36: (Functionally Unrelated Single Nucleotide Polymorphisms (SNPs))*

Claim 1: An isolated nucleic acid molecule comprising SEQ ID NO: 1 with a single polymorphic change at one of the positions as shown below:

Polymorphism	*Position*	*Change from SEQ ID NO: 1 to:*
1	*10*	*G*
2	*27*	*A*
3	*157*	*C*
4	*234*	*T*
5	*1528*	*G*
6	*3498*	*C*
7	*13524*	*T*
8	*14692*	*A*

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

According to the description, SEQ ID NO: 1 is 22,930 nucleotides in length. The SNPs 1-8 are not characterized, that is, no common property or activity has been disclosed.

SEQ ID NO: 1 has been described in the prior art but no specific function has been identified.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the SNPs 1-8 share a common property or activity. The fact that all point mutations are within a defined sequence (SEQ ID NO: 1) is not sufficient to establish unity of invention since SEQ ID NO: 1 has already been described in the prior art, and no functional relationship exists among the different SNPs claimed. For this reason, the SNPs of claim 1 lack unity of invention.

One possible grouping would be:

Inventions 1-8: SNPs 1-8.

10.57 *Example ~~35~~37: (Molecules Which Share a Common Function not Linked to a Common Structure)*

Claim 1: A fusion protein comprising carrier protein X linked to a polypeptide having SEQ ID NO 1, 2, or 3.

The description discloses that carrier protein X is 1000 amino acids in length and functions to increase the stability of the fusion proteins in the blood stream. SEQ ID NOs: 1, 2, and 3 are small epitopes (10-20 residues in length) isolated from

different antigenic regions of E.coli*. SEQ ID NOs: 1, 2, and 3 do not share any significant common structure.*

Both the structure of protein X and its function as a carrier protein are known in the prior art. Fusion proteins that generate an antigenic response to E. coli *are known in the prior art.*

The fusion proteins of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity, as determined by the Authority (see paragraph 10.05). Some Offices may regard claim 1 as a Markush grouping.

In this example, the only common structure shared by the fusion proteins is carrier protein X. The fusion proteins share a common property, i.e., generation of an antibody response specific for *E. coli*. However, immunization with the carrier protein alone does not result in the common property; SEQ ID NO: 1, 2, or 3 is required for this property.

No special technical feature exists among the three fusion proteins. The fact that all the fusion proteins have a common property is not sufficient to establish unity of invention because (1) SEQ ID NOs: 1, 2, and 3, which impart the common property, do not share a significant structural element, (2) the common structure, carrier protein X, does not impart the common property, and (3) fusion proteins that generate an antigenic response specific for *E. coli* are known in the prior art.

One possible grouping would be:

Invention 1: Fusion protein comprising carrier protein X and SEQ ID NO: 1.

Invention 2: Fusion protein comprising carrier protein X and SEQ ID NO: 2.

Invention 3: Fusion protein comprising carrier protein X and SEQ ID NO: 3.

10.58 *Example ~~36~~38~~:~~ (Multiple Nucleic Acid Molecules Which Share Common Structure and Encode Proteins with Common Property)*

Claim 1: An isolated nucleic acid selected from SEQ ID NO: 1, 2, or 3.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the three nucleic acids encode dehydrogenases that include a conserved sequence motif defining the catalytic site and the dehydrogenase function of these proteins. The three nucleic acids were isolated from three different sources (mouse, rat, and human). The description clearly shows that these three nucleic acids are homologous based upon their overall sequence similarity (85-95% identity) at both the nucleotide and amino acid sequence levels.

The prior art describes a nucleic acid molecule isolated from monkeys, which has high sequence similarity (e.g., 90%) to SEQ ID NO: 1. The monkey nucleic acid encodes a dehydrogenase that includes the catalytic site defined by the conserved motif.

The nucleic acids of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

Rule 13.2 requires that the technical feature shared between the inventions defines a contribution over the prior art.

A same or corresponding technical feature shared among the claimed nucleic acid molecules resides in their common property (encoding dehydrogenases) and their shared structural element that is essential to the common property (the conserved motif). However, a nucleic acid molecule which encodes a dehydrogenase and contains the shared structural element has already been isolated from a different source (monkeys). Thus, the technical feature is not special because the functional and structural similarity between the claimed molecules cannot form the contribution that the group of inventions as a whole makes over the prior art. Therefore, unity of invention is lacking (*a posteriori*).

On the other hand, if the only prior art available disclosed a nucleic acid molecule encoding a dehydrogenase that lacked the catalytic site defined by the conserved sequence motif, the technical feature would be special and SEQ ID NOs: 1, 2, and 3 would have unity of invention.

A possible grouping would be:

Invention 1: Nucleic acid of SEQ ID NO: 1

Invention 2: Nucleic acid of SEQ ID NO: 2

Invention 3: Nucleic acid of SEQ ID NO: 3

10.59 *Example ~~37~~39:~~ ~~(~~DNA Encoding Receptors with Partial Structural Identity and Asserted Common Property~~)~~*

Claim 1: A polynucleotide encoding a guanosine triphosphate-binding protein coupled receptor (GPCR) comprising a nucleotide sequence selected from the group consisting of the odd-numbered SEQ ID NOs from SEQ ID NO: 1 to SEQ ID NO: 2069.

The description identifies a conserved sequence of 15 amino acid residues found in several known GPCR molecules that is asserted to be essential to the GPCR function. A consensus polynucleotide sequence encoding the conserved amino acid sequence was generated. A database containing human genome sequences was searched using the consensus polynucleotide sequence. Using this system, 1035 polynucleotide sequences were identified, which are asserted to encode GPCR molecules that include the conserved sequence.

The prior art discloses human GPCR molecules that contain the conserved sequence of 15 amino acid residues, as well as the polynucleotide sequences that encode the conserved 15 amino acid sequence.

The common technical feature among the 1035 polynucleotide sequences is the consensus polynucleotide sequence that encodes the common sequence of 15 amino acid residues. This technical feature is not special because the consensus polynucleotide sequence was known and therefore cannot form the contribution that the group of inventions as a whole makes over the prior art. Consequently, the 1035 different polynucleotides lack unity of invention (*a posteriori*).

One possible grouping would be:

Inventions 1-1035: Polynucleotides based on SEQ ID NOs: 1-2069 (odd-numbers)

If the description did not assert, or it was not readily apparent, that the conserved sequence of 15 amino acid residues was essential to the GPCR function, unity of invention could be lacking in the absence of any relevant prior art.

On the other hand, given the assertion in the description, in the absence of the prior art in the example, the groups would have had unity of invention.

Dependent Claims Adding Substantial Features Which Diverge from the Inventive Concept (Lack of Unity a posteriori*) – Example 40*

10.59A *Example 40*

Claim 1: A humidifier, comprising:

a tub to contain a supply of water; an inlet to receive a flow of breathable gas, the inlet configured to direct the flow over the supply of water to humidify the flow;

an outlet connectable to a conduit; a wicking element provided in the tub; and

a heating element extending from the inlet to the outlet, wherein the heating element is configured to contact the supply of water.

Claim 2: A humidifier according to claim 1, wherein the heating element comprises:

at least one resistive wire having a first end and a second end;

an insulating layer between the first and second ends; and

an outer coating surrounding the at least one resistive wire and the insulating layer.

Claim 3: A humidifier according to claim 1, further comprising a support in the tub to support the wicking element, wherein the support is a tubular support and the wicking element is provided on an outer surface of the tubular support.

In this example the features of claim 1 are found to be disclosed in the prior art and are hence not novel and not inventive. In addition, claims 2 and 3 define substantially different special technical features and are further directed to substantially different technical aspects. Claims 2 and 3 lack unity *a posteriori*, as long as this consideration is consistent with paragraph 10.04 which states that “If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the applicant”.

Lack of Unity of Invention in a Single Independent Claim – Examples 41 and 42

10.59B *Example 41*

Claim 1: A method of detecting bladder cancer in a subject comprising:

(a) contacting a sample obtained from the subject with one or more agents that detect expression of at least one of the markers chosen from MAGEA 10, DSCR8, MMP 12, CXCL9, DSCR8, KRT81, LOC729826, PTHLH, MMP1 1, and S100A7; and;

(b) contacting a non-cancerous cell, e.g. a non-cancerous cell from bladder tissue or a non-cancerous bladder cell line, with the one or more agents that detect expression of at least one of the markers listed above;

wherein a higher level of expression of one or more of the markers in the sample compared to the non-cancerous cell indicates that the subject has bladder cancer.

According to Markush practice, a claim defining alternatives can be unified when the alternatives share a common property or activity and either have a common structure or belong to a recognized class of compounds.

A "recognized class of compounds" must be a class of compounds already known based on the prior art (e.g., TNF inhibitors, tumor suppressors, serine threonine kinases) that a skilled addressee would expect will behave in the same way.

In the present claim, while the alternatives have a common property, namely their role as a biomarker for bladder cancer, the alternatives do not have a common structure; and are not considered to be a recognized class of chemical compounds because each of the biomarkers identified come from diverse gene/protein families. Therefore, each biomarker is considered to be a separate invention.

Also note that the association between bladder cancer and biomarkers has been disclosed in the prior art and cannot itself represent a special technical feature.

10.59C *Example 42*

Claim 1: A method of forming an orthotic for a patient's foot, the method comprising the steps of:

preparing an orthotic template for the foot wherein the template extends between a heel end and a toe end, preparing the template including the steps of:

attaching an upper layer of thermoplastic material to a lower layer of thermoplastic material or heating the prepared orthotic template to a predetermined temperature.

The claim can be written into two different independent claims (a) or (b).

(a) A method of forming an orthotic for a patient's foot, the method comprising the steps of:

preparing an orthotic template for the foot wherein the template extends between a heel end and a toe end, preparing the template including the steps of:

attaching an upper layer of thermoplastic material to a lower layer of thermoplastic material.

or

(b) A method of forming an orthotic for a patient's foot, the method comprising the steps of:

preparing an orthotic template for the foot wherein the template extends between a heel end and a toe end, preparing the template including the steps of:

heating the prepared orthotic template to a predetermined temperature.

The feature of “forming an orthotic for a patient’s foot” by “preparing an orthotic template for the foot wherein the template extends between a heel end and a toe end” is common to claims (a) and (b).

However, if it can be established that this common feature is known in the art, then there will be a lack of unity of invention *a posteriori* within the one claim.

Complex Claim Sets with Overlapping Features – Example 43

10.59D *Example 43*

Often claims contain features that overlap with the features of other claims. Determination of unity of invention in these cases requires careful consideration. The lack of unity observation will depend on the facts of the case, and care should be taken that an objection is not raised on the basis of a narrow, literal or academic approach, as warned against in paragraph 10.04.

Claim 1: A turbine rotor blade formed to provide a semicircular shaped cross section.

Claim 2: A turbine rotor blade as claimed in claim 1 comprising alloy Z

Claim 3: Alloy Z.

Independent claim 1 is directed to a turbine blade. The feature of ‘the blade formed to provide a semicircular shaped cross section’ is considered to be the special technical feature of this claim.

Independent claim 3 is directed to an “alloy Z” and this is considered to be the special technical feature of this claim.

Therefore, independent claims 1 and 3 lack unity *a priori* as there is no special technical feature common to these claims.

If claim 1 is novel and inventive, then, according to paragraph 10.07, it follows that there is unity of invention in respect of any claims that depend on the novel. That is, unity of invention exists between claims 1 and 2.

If after a review of the prior art claim 1 is found to be not novel and not inventive; that is if “a turbine rotor blade formed to provide a semicircular shaped cross section” is known in the art, and alloy Z is found to be novel and inventive, it follows that there is unity of invention between claims 2 and 3, as both contain a common special technical feature, namely alloy Z.

However, if alloy Z is not novel or inventive, then any lack of unity of invention between claims 2 and 3 would be a purely academic exercise.

In all of the above scenarios, independent claims 1 and 3 lack unity a priori as there is no special technical feature common to these claims. However, the appropriate grouping of the claims will depend on the facts of the case.

10.60 to 10.88 *[No change]*

[End of Annex and of Circular]