

ANNEX 2: Comments of the JPO

JPO Comments on Claim 1 of Example I

1. Challenges faced in automated search of the prior art

(a) Prior analysis on unity of invention

To establish a complete search, it is necessary to make all queries that correspond to each polymorphism, and to use them for searching the prior art. Before an examiner starts to search the prior art, it is necessary to clarify whether the examiner may limit the scope of the search due to the lack of unity of invention.

(b) External database search

While JPO has an in-house dbSNP database provided by NCBI, there are several other SNPs databases available on the Internet. To conduct a complete search, it is necessary to search such external databases. While some databases are searchable via the Internet, these databases lack the necessary security to permit a complete search of the claimed inventions.

(c) Association between gene X and disease X

If an association between gene X and disease X is known, it is probable that there is an association between the polymorphism of gene X and disease X even though there is no prior art describing polymorphism in gene X. As this should be considered in determining whether the invention involves an inventive step, a search of the association is required.

2. Challenges faced in comparing prior arts

(a) Polymorphism and scope of the disclosure in the prior art

Even if the prior art does not disclose that there is polymorphism in gene X, it may be possible to determine that existence of the polymorphism is essentially described in prior art as a gene obviously has polymorphism. The determination should be taken into account when assessing unity of invention and inventive step.

(b) Association between gene X and disease X

If an association between gene X and disease X is known, it is probable that there is an association between polymorphism of gene X and disease X even though there is no prior art describing polymorphism in gene X. As this should be considered in determining whether the invention involves an inventive step, a search of the association is required.

3. Challenges faced in determination on the requirement of unity

(a) Existence of the polymorphism site in the gene and problems to be solved by the invention and common new matter corresponding to the problems they are to solve

In order to meet the requirement of unity of invention, an invention must be identified as a single technical idea based on statements of the claim. Furthermore, one of the following conditions must be met:

(a) the group of inventions all solve a common technical problem unsolved until the time of filing, or

(b) the group of inventions have in common a substantial part of the matters that define the invention. (Guidelines Part I, Chap. 1, 2.2.2.1.(4)(ii))

In this example, it is obvious that each invention based on statements of the claim does not solve a common technical problem unsolved until the time of filing because the polynucleotide shown as SEQ ID NO: 1 in the description is publicly known. An examiner should be aware of whether the discovery of a single nucleotide polymorphism in a known gene should be deemed to be a technical problem to be solved by the invention which was unsolved until the time of filing.

(b) Association between gene X and disease X

Where the association between gene X and disease X is known, an examiner should be aware of the fulfillment of requirement of unity of invention because it is considered obvious that there is polymorphism associated with disease X in gene X, and polymorphism associated with disease X is not a common technical problem to be solved by the invention which was unsolved until the time of filing.

Reference:

(PCT Preliminary Examination Guideline III-7.6.) 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 common inventive concept which appears novel and involves inventive step, then the objection of lack of unity does not arise. To determine the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case should be considered on its merits, the benefit of any doubt being given to the applicant.

4. Challenges faced in determination on the requirements of clarity, enablement, and industrial applicability

(a) Scientific reliability of the association between alleles and disease X

Whether or not the difference of frequencies of SNP emergence in the groups of the population can be deemed as scientific proof of the association between gene X and disease X should be examined.

(b) Allele variants that have no specification concerning association with the presence of disease

The examiners should be aware of lack of industrial applicability and enablement.

JPO Comments on Claim 2 of Example I

See comments of claim 1 of Example I

JPO Comments on Claim 1 of Example II

1. Challenges faced in automated search of the prior art

(a) Selection of appropriate databases

As an examiner may have to search prior art concerning association between gene X and response to treatment by the drug, it is necessary to find proper databases.

(b) External database search

As JPO has no Haplotype database, a search of external databases will be necessary to conduct a complete search. While some databases are searchable via the Internet, these databases lack the necessary security to permit a complete search of the claimed inventions.

(c) Association between gene X and disease X

If an association between gene X and disease X is known, it is probable that there is an association between the polymorphism of gene X and disease X. Even though there is no prior art describing polymorphism in gene X, there is enough probability of an association between the polymorphism of gene X and disease X. Since this should be considered in determining whether the invention involves inventive step, a search of the association is required.

2. Challenges faced in comparing prior arts

(a) Conclusion of patentability of claim 1

It is obvious that claim 1 does not have novelty since gene X containing SEQ ID NO: 1 and Haplotype 1 was publicly known prior to the filing of the patent application.

(b) Examiner's response when Haplotype 1 is excluded from claim 1

Because gene X containing SEQ ID NO: 1 and Haplotype 1 was publicly known prior to the filing of the patent application, an examiner should be aware that Haplotypes 2-5 do not fulfill the requirement of unity of invention.

It is doubtful that claimed long polynucleotides are able to detect the difference between haplotypes since each polynucleotide is 3,267 nucleotides in length and too long to hybridize. If the nucleotide is only an allele variant of gene X and Haplotype 1 is publicly known prior to the filing of the patent application, discovery of the allele variant of the gene per se is not deemed to be a common technical problem to be solved by the inventions which had been unsolved until the time of filing.

Therefore the examiner should determine unity of invention and enablement prior to novelty and inventive step.

(c) Association between gene X and response to treatment by drug Y and drug metabolism

The claim may not involve inventive step if a person skilled in the art is deemed to have enough motivation to seek haplotypes associated with disease X or drug metabolism.

3. Challenges faced in determination of the requirement of unity

(a) Haplotype 2-5

An examiner should be aware that each haplotype does not solve a common technical problem unsolved until the time of filing and does not fulfill the requirement of unity of invention.

4. Challenges faced in determination of the requirements of clarity, enablement, and industrial applicability

(a) Allele variants that have no specification concerning association with the presence of disease

An examiner should be aware of lack of industrial applicability and enablement.

(b) Enablement of the claimed polynucleotide

It is doubtful that claimed long polynucleotides detect differences between haplotypes since each polynucleotide is 3,267 nucleotides in length and too long to hybridize. If the claimed nucleotide is only an allele variant of gene X, it seems very hard for to claim 1 to fulfill the requirement of inventive step.

JPO Comments on Claim 2 of Example II

1. Challenges faced in automated search of the prior art

None.

2. Challenges faced in comparing with the prior art

(a) Conclusion on patentability for claim 2

Obviously claim 2 does not involve an inventive step, because gene X containing sequence SEQ ID NO: 1 and Haplotype 1 was publicly known prior to the filing of the patent application. This determines the presence of the nucleotides present at positions 23, 47, 89, 213, 605, 788, and 1592 of the individual's copy of gene X, wherein the position numbers are determined by comparison to SEQ ID NO: 1.

3. Challenges faced in determination on the requirement of unity

None.

4. Challenges faced in determination on the requirements of clarity, enablement, and industrial applicability

As claim 1 does not involve inventive step, the reason for rejection can be transmitted without examining clarity, enablement, and industrial applicability.

If claim 2 claims the response of patients with disease X to treatment by drug Y which acts on disease X, an examiner should be aware of the reliability of the association between the haplotypes and response of patients with disease X.