Trilateral Project B3b

Comparative study on biotechnology patent practices

Theme: Patentability of DNA fragments

1. Introduction

In the face of rapid progress of biotechnology including areas relating to DNA fragments, updating and improving the comparative study (project 24.1) done by the three offices is valuable.

DNA fragments are most interesting issue as DNA fragments reveal very interesting and challenging aspect of patentability and attract public attention through a potential deep impact on the academy and industry.

Therefore, at the last Trilateral Meeting in Miami, the Trilateral Offices agreed to continue the comparative study in biotechnology focusing on selected areas covered in the previous comparative study, including DNA fragments, in an efficient manner in a shorter period of time.

2. Provision

Applicable Sections / Articles of respective Patent Laws

	Industrial applicability (Utility*)	Enablement requirement	Novelty	Inventive step Non-obviousness	Written description
USPTO	***101**	**112**	**101**	**103**	**112**
EPO	**57**	**83**	**54**	**56**	**-**
JPO	**29(1)**	**36(4)**	**29(1)III**	**29(2)**	**-**

(*): In the USA, industrial applicability is not coextensive with utility requirement of Title 35 USC. National stage applications are not examined whether an invention has industrial applicability or not.

3. Hypothetical Cases

The three offices examined the following requirement in each case.

The filing date of these cases is supposed to be January 1, 1999.

3.1 Question1 UTILITY (INDUSTRIAL APPLICABILITY), NOVELTY, INVENTIVE STEP (NON OBVIOUSNESS), ENABLEMENT REQUIREMENT (SUFFICIENCY OF DISCLOSURE), etc.

Outline of Case A

[Claim]

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:1.

The claimed polynucleotide is 500bp cDNA obtained from human liver cDNA library. The polynucleotide can be used as a probe in one of the steps to obtain the full-length DNA, though there is no description of the function or biological activity of the DNA and its corresponding protein.

There is no known nucleotide sequence with high similarity to that of SEQ ID NO:1.

Outline of Case B

[Claim]

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:2.

The claimed polynucleotide is 500bp cDNA obtained from human liver cDNA library and assumed to be part of a structural gene encoding human protein X as a result of similarity search. (The polynucleotide demonstrated 95% homology to part of a structural gene encoding rat protein X. The deduced amino acid sequence also showed 95% homology to amino acid sequence of rat protein X.)

The polynucleotide can be used as a probe in one of the steps to obtain the full-length DNA encoding human protein X.

The size of the full-length DNA encoding rat protein X is 2400bp and the DNA sequence encoding rat protein X was known.

Outline of Case C

[Claim]

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:3.

The claimed polynucleotide is 500bp cDNA obtained from human liver cDNA library. As the amino acid sequence deduced from the nucleotide sequence of SEQ ID NO:3 has a potential site of glycosylation, the polynucleotide is assumed to be part of a structural gene encoding a glycoprotein.

The polynucleotide can be used as a probe in one of the steps to obtain the full-length DNA.

There is no known nucleotide sequence with high similarity to that of SEQ ID NO:3.

Outline of Case D

[Claim]

A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:4.

The polynucleotide is 500bp long cDNA whose corresponding mRNA is expressed only in the hepatocyte of the patients with disease Y. Therefore, the polynucleotide can be used as a probe to diagnose disease Y.

There is no known DNA that is unique in the patients with disease Y or high similar to that of SEQ ID NO:4.

Outline of Case E

[Claim]

A polynucleotide comprising the nucleotide sequence of SEQ ID NO:4.

Case E differs from Case D only in terms of the expression of 'comprising' and 'consisting of'used for the claims respectively.

Outline of Case F

[Claim]

A structural gene comprising the nucleotide sequence of SEQ ID NO:2.

Case F differs from Case B in terms of the expression of the preamble language and the transition phrase.

3.2 Summary of Answers

[Utility (Industrial Applicability), Enablement Requirement, Novelty, Non-obviousness]

The three offices showed the same views that Case A, B, C, and F do not meet patentability requirements. The three offices also concurred in that there is no reason for rejection to Case D.

As a reason for rejection, the USPTO mainly points out lack of utility and enablement. On the other hand, the EPO and the JPO mainly discussed on Non-obviousness / Inventive step.

Case A, C

The USPTO and the JPO state the claimed inventions lack Utility (Industrial Applicability) and Enablement. The EPO also showed doubt on the Industrial Applicability.

The EPO and the JPO share the view that the claimed inventions do not have Inventive Step.

EPO	*JPO*	*USPTO*
A C	A C	A C

Case B, F

The USPTO mentions the claimed inventions lack Utility and Enablement.

The EPO and the JPO share the view that the claimed inventions do not have Inventive Step.

In addition, the JPO states that Case F lacks enablement.

EPO	*JPO*	*USPTO*
B F	B F	B F

Case E

Only the JPO mentions that the claimed invention does not meet enablement requirement.

(The JPO consider that the claimed invention contains long non-unique sequences as long as it contain DNA sequence of SEQ ID NO:4. On the other hand, the EPO considers that the claimed DNA cannot posses an unlimited length but a length which is still suitable for the desired purpose.)

EPO	*JPO*	*USPTO*

Case D

EPO	*JPO*	*USPTO*

[Written Description]

As USPTO practice with respect to the application of the Written Description Requirement is currently under development, the USPTO cannot comment on written description requirement yet.

3.3 Question 2 Unity of Invention

Outline of Case G

[Claim]

- A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:1.
- A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:2.

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11. A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:11.

The claimed polynucleotides are 500bp cDNAs obtained from human liver cDNA library. These polynucleotides can be used as probes to obtain the full-length DNAs, though there is no description of the function or biological activity of the corresponding proteins.

These polynucleotides are not highly homologous to each other.

Outline of Case H

[Claim]

(Same as Case G)

The claimed polynucleotides are 500bp cDNAs obtained from human liver cDNA library. As the amino acid sequences deduced from the claimed nucleotide sequences have potential sites of glycosylation, these polynucleotides can be used as probes to obtain the full-length DNAs.

These polynucleotides are not highly homologous to each other.

Outline of Case I

[Claim]

(Same as Case G)

The claimed polynucleotides are 500bp cDNAs whose corresponding mRNAs are expressed only in the hepatocyte of the patients with disease Y. Therefore, these polynucleotides can be used as probes to diagnose disease Y.

These polynucleotides are not highly homologous to each other.

There is no known DNA that is unique in the patients with disease Y.

3.4 Summary of Answers

The three offices do not acknowledge unity of invention in Case G and H.

The EPO and the JPO acknowledge unity of invention in Case I.

EPO	***JPO***	***USPTO***
G H I	**G H I**	

4. Conclusion

Following points are revealed through this comparative study.

1. A mere DNA fragment without indication of a function or specific asserted utility is not a patentable invention.
2. A DNA fragment, of which specific utility, e.g. use as a probe to diagnose a specific disease, is disclosed, is a patentable invention as long as there is no other reasons for rejection.
3. A DNA fragment showing no unexpected effect, obtained by conventional method, which is assumed to be part of a certain structural gene based on its high homology with a known DNA encoding protein with a known function, is not a patentable invention. (EPO, JPO)
   The above-mentioned DNA fragment is unpatentable if the specification fails to indicate an asserted utility. (USPTO)
4. The mere fact that DNA fragments are derived from the same source is not sufficient to meet the requirement for unity of invention.

5. Additional conclusion

The following items are confirmed by the Trilateral Patent Offices through discussion at the Trilateral Technical Meeting in June, 2000.

1. All nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, without indication of function or specific, substantial and credible utility, do not satisfy industrial applicability, enablement or written description requirements.
2. Isolated and purified nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, of which function or specific, substantial and credible utility is disclosed, which satisfy industrial applicability, enablement, definiteness and written description requirements would be patentable as long as there is no prior art (novelty and inventive step) or other reasons for rejection (such as, where appropriate, best mode [US] or ethical grounds [EPC/JP]).

EPO

Case A

Utility (Industrial application) : questionable

This requirement normally does not cause a problem for the EPO since an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry (Article 57 EPC). In following the conventional interpretation of Article 57 EPC one could take the position that the claimed polynucleotides of 500 bp in length clearly can be made and therefore the requirement of industrial application is fulfilled. However, Article 57 EPC could also be interpreted differently by putting more weight on the "industrial" aspect thereof. Along these lines it could be argued that the right question to ask under this provision is whether "one would indeed make ESTs in any kind of industry if a specific usefulness is not known for them and therefore there is no motivation at all to make them".

If this is answered in the negative the "used" clause of the article would come into play and as ESTs do not have any specific function they cannot be used in industry. Therefore the requirement of industrial application would not be fulfilled.

Enablement requirement (sufficiency of disclosure): Yes

Since the detailed sequences of the claimed polynucleotides are given in the cases under discussion, in the view of the EPO the invention is presented in a manner sufficiently clear and complete for it to be carried out by the skilled person (Article 83 EPC). The sequence information alone is already considered sufficient to fulfil this requirement because ESTs (small polynucleotide sequences) can easily be synthesized chemically with the help of DNA synthesizer machines (note that it is irrelevant if such a method is time consuming or not). Thus, in the cases under discussion the EPO will consider this requirement to be fulfilled. With respect to sufficiency of disclosure we see no difference between the term "consisting of" and "comprising".

Novelty: Yes

There exists no problem with regard to novelty. The claimed matter is novel.

Inventive step: No

The argumentation of decision T939/92 (OJ EPO 96,309, "AgrEvo decision") could be used starting from any known DNA under the assumption that gene fragments are considered chemical compounds, as were the herbicides in the AgrEvo case.

In the AgrEvo decision the Board pointed out in general terms that the answer to the Question what the skilled person would have done in the light of the state of the art depends in large measure on the technical result he had set out to achieve, in other words he does not act out of idle curiosity but with some technical purpose in mind. In the "problem and solution approach" the technical problem which is solved by the claimed compounds, if the latter were to be assumed not to have any technical

useful property, would be the mere provision of further (or alternative) chemical compounds as such, regardless of their useful properties. In this case all known chemical compounds are equally suitable as starting material for structural modifications. Consequently, all structural similar chemical compounds that a skilled person would expect, in the light of the prior art, to be capable of being made, are equally suitable candidates for solving the above "technical problem", and would therefore all be equally suggested to the skilled person, An arbitrary choice from this host of possible solutions cannot involve an inventive step because, in order to be patentable, the selection must not be arbitrary but must be justified by the technical purpose, i.e. by a hitherto unknown or unexpected technical effect which is caused by those structural features distinguishing the compounds from the numerous other ones.

If the ArgEvo decision were applied to ESTs the corresponding technical problem would be "the provision of further (or alternative) DNA segments" . The statement of a general useful function, like use as a probe, would not make any difference in the definition of the "technical problem" because this function applies to all DNA and does not give rise to a distinguishing effect.

Case C

Utility (Industrial application): questionable

See the reason given under case A.

Enablement requirement (sufficiency of disclosure): Yes

See the reason given under case A.

Novelty: Yes

See the reason given under case A.

Inventive step : No

See the arguments listed under case A above. A glycosylation site of the amino acid sequence encoded by a specific DNA sequence does not represent an unexpected function or a surprising technical effect. Thus SEQ ID NO: 3 lacks inventive activity.

Case B

Utility (Industrial application): questionable

See the reason given under case A.

Enablement requirement (sufficiency of disclosure): Yes

See the reason given under case A.

Novelty: Yes

See the reason given under case A.

Inventive step : No

The nearest prior discloses the DNA sequence of 2400 bp encoding rat protein X, which has a known specific function and biological activity (insulin). The problem to be solved was the provision of homologous DNA sequences encoding at least fragments of the corresponding human insulin gene, which fragments can be used to obtain the fulllength human insulin gene. The use of the known rat insulin gene as probe to identify and to isolate at least parts of the corresponding human insulin gene by the use of known cross-hybridisation techniques from a cDNA library constructed from human liver must, in view of the high (95%) homology between the rat and human DNA sequences, be considered only as routine matter. In the absence of any surprising/advantageous properties involved with the claimed specific DNA sequence (fragment), inventive activity of the claimed matter cannot be acknowledged.

Case F

Utility (Industrial application): questionable

See the reason given under case A.

Enablement requirement (sufficiency of disclosure): Yes

See the reason given under case A.

Novelty: Yes

See the reason given under case A.

Inventive step: No

See the reasons given under case B.

Case E

Utility (Industrial application): Yes

See the reason given under case A.

Enablement requirement (sufficiency of disclosure): Yes

See the reason given under case A.

Novelty: cases; Yes

See the reason given under case A.

Inventive step : Yes

See the reason given under case D.

We are not able to see any difference when judging invention activity with respect to the claim language "consisting of " or "comprising". SEQ ID NO:4 has a length of 500bp and is said in the description to be useful as probe to diagnose disease Y. According to Article 69(1) EPC the description shall be used to interpret the claims. Thus, when reading said claim in context with the description it is self-evident for the skilled person that in order to be suitable as a probe, the DNA molecule which comprises SEQ ID NO:4 cannot possess an unlimited length but a length which is still suitable for the desired purpose.

There is no arbitrary selection at all as long as the basic technical element of the invention is clearly defined (SEQ ID NO:4) and present in all longer modifications of the DNA molecule, which modifications still exhibit the same functional property (being useful as probe). In this hypothetical case AgrEvo would not be the decision of choice even in the case where the full-length gene no longer (because of its length) has the function of a "probe". Such a claim would be directed to a multiplicity of useful "probe" (inventive step acknowledged) and possibly some variants not having the desired function. Other objections like "support" (Article 84 EPC) would be more useful.

Case D

Utility (Industrial application): Yes

Enablement requirement (sufficiency of disclosure): Yes

See the reason given under case A.

Novelty: Yes

See the reason given under case A.

Inventive step: Yes

The claims appear to comprise the required inventive step due to the ground that the technical usefulness (diagnosis of disease y) is not obvious.

Case G

No

The claims are directed to 11 completely different DNA sequences with unknown function and low homology to each other. According to Rule 30 EPC there should be a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Thus, there should be one common technical feature associated with DNA sequences 1-11, which contributes to the

invention. In view of the absence thereof in case G unity of invention cannot be acknowledged.

Case H

No

See the reason given under Case G.

The fact that the amino acids encoded by the DNA sequences 1-11 contain potential sites of glycosylation (case H) does not change this view. Thus, the claims of case H would also lack unity.

Case I

Yes

In case I all the different DNA sequences are associated to the solution of one specific problem, namely the diagnosis of disease y. Consequently, there exists a single general inventive concept which is capable to link the different DNA sequences. In the absence of any relevant prior art documents, unity of invention can be acknowledged.

JPO

Case A

This claim will be rejected.

Utility (Industrial applicability): No(* See Note)

Where subject matter of an invention is commercially applicable, the invention is considered to meet industrial applicability requirement.

As utility of the claimed DNA fragment is not described in the specification or cannot be inferred, the claimed invention is not commercially applicable, thus, does not meet the requirements set forth in the first sentence in Section 29(1) of the Patent Law.

*Note

Different opinion is raised that the DNA fragment would be commercialized considering of the situation that new business, offering cDNA clones which contains DNA fragments, seems appearing.

Enablement requirement: No

For an invention of a product, the invention shall be described so as to enable to make and to use the product in an industrially applicable way. (except where the product could be made and used by a person skilled in the art without such explicit description when taking into account the overall descriptions of the specification, drawings and common general knowledge as of the filing.)

In Case A, there is a description how to make the nucleotide sequence of SEQ ID NO:1. Furthermore, it is stated that the DNA can be used as a probe in one of the steps to obtain full-length DNA. However, there is no description of function or biological activity of the protein encoded by the corresponding full-length DNA. Moreover, utility of the full-length DNA cannot be assumed from common general knowledge as of the filing.

The use of DNA fragment to obtain the full-length DNA, whose corresponding protein's function nor biological activity are not known, is not considered to be industrial applicable.

In Case A, we consider there is no disclosure concerning the use of the DNA fragment in an industrial applicable way, thus the description of the invention is deemed insufficient for enabling a person skilled in the art to carry out the invention.

Novelty: Yes

Inventive Step: No

It is a well-known object to obtain cDNAs from human cells and sequence them.

It is also a well-known art to construct cDNA libraries from human organs, such as liver, and to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer.

Since there is no technical difficulty in selecting materials and constructing a cDNA library thereof, it is obvious for a person skilled in the art to create a cDNA library by a conventional method and to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer.

Therefore, even if there is no known sequence similar to the sequence of the claimed polynucleotide, for a person skilled in the art, it would have been easy to prepare DNA consisting of that sequence using conventional methods.

However, if the obtained DNA has an unexpected advantageous effect, the claimed invention may have an inventive step.

The DNA is merely assumed to be part of a structural gene and there is no description of the function or biological activity of the DNA and its corresponding protein. Therefore, the JPO cannot acknowledge disclosure of any advantageous effect of this claimed DNA, hence this invention doesn't have an inventive step.

Case C

This claim will be rejected.

Utility (Industrial applicability): No(See Note*)

See the reason given under case A.

The description that the polynucleotide is assumed to be part of a structural gene encoding glycoprotein doesn't affect judgement of commercially applicability of DNA fragment.

Enablement requirement: No

See the reason given under Case A.

The description that the polynucleotide is assumed to be part of a structural gene encoding glycoprotein doesn't affect the decision.

Novelty: Yes

Inventive Step: No

It is a well-known object to obtain cDNAs from human cells and sequence them.

It is also a well-known art to construct cDNA libraries from human organs, such as liver, and to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer, and to predict its function from the deduced amino acid sequence through a conventional prediction tool.

Since there is no technical difficulty in selecting materials and in constructing a cDNA library thereof, it is obvious for a person skilled in the art to create a cDNA library by a conventional method, to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer, and predict its function from the deduced amino acid sequence through a conventional prediction tool.

Therefore, even if there is no known sequence similar to the sequence of the claimed polynucleotide, for a person skilled in the art, it would have been easy to prepare DNA consisting of that sequence using conventional methods.

However, if the obtained DNA has an unexpected advantageous effect, the claimed invention may have an inventive step.

The DNA is merely assumed to be part of DNA encoding some kind of glycoprotein. Therefore, the JPO cannot acknowledge disclosure of any advantageous effect of this claimed DNA, hence this invention doesn't have an inventive step.

Case B

This claim will be rejected.

Utility (Industrial applicability):Yes

Enablement requirement: Yes

Novelty: Yes

Inventive Step: No

[Reason 1]

It is a well-known object to prepare human DNAs encoding proteins.

It is also common general knowledge to isolate the human DNA encoding a certain protein by a hybridization method, using as a probe a partial nucleotide sequence of a mammal other than human encoding the same protein, since DNA sequences encoding a certain protein have in general high homology among mammalians.

Therefore, it is obvious to isolate the DNA encoding human protein X using the partial DNA sequence encoding rat protein X as a probe.

However, if the obtained DNA has an unexpected advantageous effect, the claimed invention may have an inventive step.

The DNA is merely assumed to be part of a structural gene. Therefore, the JPO cannot acknowledge disclosure of any advantageous effect of this claimed DNA, hence this invention doesn't have an inventive step.

[Reason 2]

It is a well-known object to obtain cDNAs from human cells and sequence them.

It is also a well-known art to construct cDNA libraries from human organs, such as liver, and to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer, and to predict its function from the DNA sequence and the deduced amino acid sequence through a similarity search.

Since there is no technical difficulty in selecting materials and in constructing a cDNA library thereof, it is obvious for a person skilled in the art to create a cDNA library by a conventional method, to analyze the sequence of cDNA randomly chosen from the library with the use of an automated sequencer, and to predict its function through a similarity search, using FASTA, BLAST etc.

However, if the obtained DNA has an unexpected advantageous effect, the claimed invention may have an inventive step.

The DNA is merely assumed to be part of a structural gene. Therefore, the JPO cannot acknowledge disclosure of any advantageous effect of this claimed DNA, hence this invention doesn't have an inventive step.

Case F

This claim will be rejected.

Utility Industrial applicability): Yes

Enablement Requirement: No

To actually obtain the full-length DNA of the claimed invention, undue experiments would be necessary for the person skilled in the art, such as constructing a cDNA library containing full-length DNAs.

Novelty: Yes

Inventive Step: No

The reason under Case B applies.

Case E

This claim will be rejected.

Utility (Industrial applicability): Yes

Enablement Requirement : No

The claimed polynucleotide contains a long non-unique sequence along with the nucleotide sequence of SEQ ID NO:4.

In the field of biotechnology, it is a common general knowledge that a polynucleotide sequence in part unique to a certain DNA but in other long part non-unique to the DNA cannot be used as a diagnostic probe for detecting a specific nucleotide sequence, because the non-unique portion would prevent the unique portion from hybridizing to the corresponding DNA and therefore the nucleotide sequence as a whole could not hybridize to that DNA.

Thus, those polynucleotides with long non-unique sequences included in the claim cannnot be used as diagnostic probes, and therefore the claimed invention does not meet the enablement requirement.

(Even in this Case E, it doesn't mean that all polynucleotides with additional nucleotides don't meet the enablement requirement.)

Novelty: Yes

Non-obviousness: Yes

Case D

This claim is patentable.

Utility (Industrial applicability): Yes

Enablement requirement: Yes

Novelty: Yes

Non-obviousness: Yes

Case G

No

These claims will not have Unity of Invention.

As there are so many known polynucleotides which are derived from human liver, the fact that these DNA sequences have the same source doesn't mean that these sequences have the same technical problem to be solved because the technical problem must be the one unsolved before the filing.

Furthermore, it could not be said that substantial parts of the matters being to be stated in the claims are the same since the claimed polynucleotides are not highly homologous to each other.

Case H

No

These claims will not have Unity of Invention.

As there are so many known polynucleotides encoding glycoproteins, the fact that these DNA sequences have the same source doesn't mean that these sequences have the same technical problem to be solved because the technical problem must be the one unsolved before the filing.

Furthermore, it could not be said that substantial parts of the matters being to be stated in the claims are the same since the claimed polynucleotides are not highly homologous to each other.

Case I

Yes

These claims will have Unity of Invention.

Since all of the claimed inventions are related to specific DNA in the patients with disease Y, the industrial fields of application are considered to be the same.

And all of the claimed inventions have the same problem to be solved that they provide multiple group of DNAs which are specific to the patients with disease Y for the first time because such DNA was not known before filing.

USPTO

Case A

Utility: No

The SEQ ID NO: 1 polynucleotide of claim 1 lacks a specific asserted utility under 35 USC 101. See 35 USC 101 Utility Guidelines, example 9 "DNA Fragments."

Although the polynucleotide is disclosed to be useful as a probe to obtain the full-length cDNA comprising a structural gene, the structure and function of the protein encoded by that gene are unknown. The only asserted utility for the claimed DNA is a method of obtaining the full-length structural DNA. Thus to determine whether or not this method is a specific utility, it must be determined whether or not the full-length DNA has a specific utility. Here there is no asserted utility for the full-length DNA except to encode a protein for which there is no specific asserted utility nor a well-established utility. A starting material which can only be used to produce a final product does not have a specific asserted utility in those instances where the final product is not supported by a specific utility.

Enablement: No

The SEQ ID NO: 1 polynucleotide of claim 1 necessarily lacks enablement for use of the polynucleotide since the polynucleotide lacks utility.

Novelty: Yes

Non-obviousness: Yes

Case C

Utility: No

The SEQ ID NO: 3 polynucleotide lacks utility for the same reasons given in the discussion of Case A. No specific utility was asserted for SEQ ID NO;3 polynucleotide and the fact that the polynucleotide is assumed to be part of a structural gene encoding a glycoprotein is not sufficient to support a well-established specific utility.

Enablement: No

The SEQ ID NO: 3 polynucleotide lacks enablement for the same reasons given in the discussion of Case A

Novelty: Yes

Non-obviousness: Yes

Case B

Utility: No

It depends on the disclosure in the specification of the application. If the specification asserts that because of the homology of the polynucleotide SEQ NO: 2 to the rat structural gene, the polynucleotide has utility for isolating the human gene encoding the human protein corresponding to rat protein X, the utility requirement may have been satisfied. Absent such an assertion, the polynucleotide of claim 1 lacks a specific asserted utility under 35 USC § 101.

Enablement: No

It depends on whether the claimed polynucleotide has or lacks a specific utility. If the polynucleotide lacks specific utility, the specification fails to teach one of skill in the art to use the invention as required by 35 USC § 112, first paragraph.

Novelty: Yes

Non-obviousness: Yes

The claim is drawn to the specific polynucleotide consisting of SEQ NO: 2. There does not appear to be any teaching or motivation in the prior art to modify the rat polynucleotide to achieve the invention as a whole, that is, SEQ ID NO: 2.

Case F

Utility: No

It depends. The structural gene comprising the nucleotide sequence of SEQ ID NO:2 lacks utility for the same reasons discussed above for Case B.

Enablement: No

The structural gene comprising the nucleotide sequence of SEQ ID NO:2 lacks enablement for the same reasons discussed above for Case B.

Novelty: Yes

Non-obviousness: Yes

Case E

Utility: Yes

Enablement: Yes.

Although the claimed polynucleotides are broader in scope than those claimed in case D, an analysis of the Wands factors indicates that the claim is enabled for its full scope.

Novelty: Yes

Non-obviousness: Yes

Case D

Utility: Yes

SEQ ID NO: 4 has utility as a specific probe for the diagnosis of disease Y.

Enablement; Yes

Novelty: Yes

Non-obviousness: Yes

Case G, H, I

No

Case G, H and I do not have unity of invention since the eleven polynucleotides are not highly homologous to each other. The differing descriptions do not affect the interpretation of the claims relative to unity of invention. See "Examination of Patent Application Containing Nucleotide Sequences" 1192 OG 68 (November 19, 1996), which provides for the examination of up to ten sequences in a single application, including applications filed under the Patent Cooperation Treaty and under 35 USC 371 per 37 CFR 1.475 and 1.499. However, it is within the examiner's discretion to examine the eleventh sequence if it does not create an undue burden.