ANNEX 1: Comments of the USPTO

Questionnaire for Comparative Study on "Reach-Through Claims"

Questions:

1. Do the following claims satisfy clarity, enablement, support and written description requirements? If not, explain why.
2. Do the following claims satisfy the industrial applicability or utility requirements? If not, explain why.
3. If there are any comments on the kind of evidence, argument, and/or claim amendment that may overcome any rejection for failure to satisfy the requirement of 1 and/or 2 above, please state them.

Fact Pattern	Claim	Utility	Written Description	Enablement	
				"How to Make"	"How to Use"
1	1	N	Y	Y	N
	2	N	N	N	N
	3	N	N	N	N
	4	N	N	N	N
	5	N	Y	Y	N
2	1	Y	Y	Y	Y
	2	Y	Y	Y	Y
	3	Y	N	N	N
	4	Y	N	N	N
	5	Y	Y	Y	Y
3	1	N	Y	Y	N
	2	N	Y	Y	N
	3	N	N /Y(scope)	N/Y (scope)	N
	4	N	N	N	N
	5	N	N	N	N
	6	N	Y	Y	N
4	1	Y	Y	Y	Y
	2	Y	Y	Y	Y
	3	Y	N/Y (scope)	N/Y (scope)	N/Y (scope)
	4	Y	N/Y (scope)	N/Y (scope)	N/Y (scope)
	5	Y	Y	Y	Y
	6	Y	Y	Y	Y

Example **1:**

Outline of the Specification:

The application describes the isolation of a protein (SEQ ID NO:1) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any ligand for the receptor of SEQ ID NO: 1 or any particular biological or biochemical process in which this receptor is involved.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claim. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure.

Furthermore, although the receptor of SEQ ID NO: 1 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 1.

35 U.S.C. § 101: Utility

To comply with 35 U.S.C. § 101, the claimed invention must have at least one specific, substantial, and credible utility that is either asserted in the specification or well-established.

In this example, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins and that different R-receptors are important to a wide variety of physiological processes. Assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. Because there is no indication of a specific and substantial use for the claimed member of the R-receptor family of proteins, this claim does not comply with the utility requirement of 35 U.S.C. § 101.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

35 U.S.C. § 112, first paragraph: Written Description

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations

using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

This claim meets the requirement for an adequate written description of the claimed invention because the scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. Factors to be considered in determining whether any necessary experimentation is "undue" include the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the presence or absence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph because given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. However, this claim does <u>not</u> meet the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph because there is no disclosed use that would meet the utility requirement of 35 U.S.C. § 101 (see utility discussion, above).

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

This claim does not comply with the utility requirement for the reasons noted with respect to claim 1. There is no specific, substantial, and credible utility for the receptor of claim 1. Furthermore, the specification does not assert any specific, substantial, and credible utility for an agonist (activating compound) of the receptor of claim 1. Therefore the claimed method of identifying an agonist (activating compound) of the receptor of claim 1 does not comply with the utility requirement.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would recognize a specific, substantial, and credible utility for the agonist identified by the claimed method. A method of detecting a useful product has utility; a method of detecting a product that has no known utility is not useful.

35 U.S.C. § 112, first paragraph: Written Description

The claim is directed to a method of identifying an agonist that activates the receptor of claim 1. While the specification does provide an adequate written description of the receptor of claim 1 (as noted above), there is no disclosure of the activity of the receptor, nor any method for analyzing any such activity. There is no description of the identifying characteristics for recognizing that a candidate compound activates the receptor. There is no description of an actual reduction to practice, each step of the claimed method, or distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. Therefore, the claim fails to comply with the written description requirement.

35 U.S.C. § 112, first paragraph: Enablement

The claim is directed to a method of identifying an agonist that activates the receptor of claim 1. The specification does not provide any guidance with respect to the activity of the receptor, nor any working examples. One skilled in the art would first have to determine the activity of the receptor in order to develop the claimed assay. The claim does not comply with the enablement requirement because the skilled artisan would not have been able to make the claimed assay without undue experimentation.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed methods fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph. See the discussion of the utility requirement for objective evidence that might overcome this rejection.

3. An isolated and purified receptor agonist identified by the method of claim 2

35 U.S.C. § 101: Utility

This claim fails to comply with the utility requirement for the reasons set forth with respect to claims 1 and 2.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to an agonist identified by the method of claim 2. However, no structural or specific functional characteristics of such an agonist are provided, nor is there any indication that the applicant had possession of any agonist. This situation is analogous to that of

Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

35 U.S.C. § 112, first paragraph: Enablement

The specification fails to disclose any particular structure for the claimed agonist. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to prepare the claimed agonist. Furthermore, an assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed agonist fails to meet the requirements of the "how to use" prong of 35 U.S.C. § 112, first paragraph.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim does not comply with the utility requirement of 35 U.S.C. § 101 for the reasons set forth with respect to claims 1 and 2, above. Furthermore, the instantly claimed invention is drawn to a method of treating an undisclosed disease. Since the fact pattern fails to establish what disease, if any, would be treatable by the undisclosed agonist, the claimed treatment does not encompass a specific, substantial, and credible utility.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would have known what disease(s) would have been treatable with the undisclosed agonist.

35 U.S.C. § 112, first paragraph: Written Description

This claim does not comply with the written description requirement for the reasons set forth with respect to claims 2 and 3. Further, the claimed method requires treatment of an unspecified disease. One skilled in the art would conclude that the artisan was not in possession of the claimed method of

use.

35 U.S.C. § 112, first paragraph: Enablement

This claim does not comply with the "how to make" prong of the enablement requirement for the reasons set forth with respect to claims 2 and 3. Furthermore, no information is presented as to how the undisclosed agonist would have been administered to treat an unspecified disease. Thus, the skilled artisan would not have been able to practice the steps required by the claimed invention.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed method fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph.

Objective evidence might overcome this rejection if it shows by a preponderance of the evidence that, at the time of filing, the activity and use of the claimed R-receptor of claim 1 as well as its association with some disease state was known. Further, to show utility of the claimed method, objective evidence should provide some indication that increasing or enhancing the activity of the R-receptor would result in treatment of the unspecified disease.

5. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim would not meet the utility requirement of 35 U.S.C. § 101 for the reasons set forth with respect to claim 1. Given that there is no specific, substantial, and credible utility for claimed receptor, there would be no specific and substantial practical benefit or utility for detecting the receptor with the claimed antibody or to use the antibody in any other manner.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one skilled in the art would have been able to use routine and well known methods to prepare an antibody to such a target.

However, this claim does not meet the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, since there is no disclosed use that would meet the utility requirement of 35 U.S.C. § 101.

Example 2

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 2) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The relationship between the absence of this receptor and the occurrence of obesity is determined by experimental measures, and there is no doubt that the activation of this receptor can treat or inhibit obesity.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claims. The description also teaches a method of measuring the biochemical and binding activity of this specific receptor, and there is no doubt that these activities can be measured. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure. Furthermore, although the receptor of SEQ ID NO: 2 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 2.

35 U.S.C. § 101: Utility

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C.
§ 101. In the instant case, the presence or absence of the receptor is useful in diagnostic methods relating to obesity.

35 U.S.C. § 112, first paragraph: Written Description

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. The claim meets the "how to use" prong of 35 U.S.C. § 112, first paragraph, since the receptor's presence or absence may be used in diagnostic methods relating to obesity.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
preparing a candidate compound,
contacting a cell which expresses said receptor on its surface with said candidate compound, and
determining whether said candidate compound activates the receptor of claim 1,
wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

The treatment of obesity using agonist compounds identified by the claimed method is a specific, substantial, and credible utility, and therefore the claim complies with the utility requirement of 35 U.S.C. § 101.

35 U.S.C. § 112, first paragraph: Written Description

The claimed method of identifying agonist compounds meets the requirement for an adequate written description as required by 35 U.S.C. § 112, first paragraph, because the specification teaches methods of screening for compounds that activate this receptor and the receptor's activity is disclosed.

35 U.S.C. § 112, first paragraph: Enablement

This claim also meets the requirements for how to make and use the claimed method of identifying agonist compounds because the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1, and the receptor's activity is disclosed.

3. An isolated and purified receptor agonist identified by the method of claim 2.

35 U.S.C. § 101: Utility

The claimed receptor agonist meets the requirement for utility as set forth in 35 U.S.C. § 101 for reasons set forth above in the analysis of claims 1 and 2.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to an agonist identified by the method of claim 2. However, no structural or specific functional characteristics of such an agonist is provided, nor is there any indication that the artisan actually implemented the method of claim 2 so as to identify any agonist. This situation is analogous to that of *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

35 U.S.C. § 112, first paragraph: Enablement

The instant fact pattern fails to disclose any particular structure for the claimed agonist. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to have prepared the claimed agonist without undue experimentation. Furthermore, an assay for *finding* a product is not equivalent to a positive recitation of *how to make* such a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph.

While the claimed agonist meets the utility requirement of 35 U.S.C. § 101, the claimed invention does not comply with the "how to use" prong of 35 U.S.C. § 112, first paragraph. The specification does not teach how to administer the claimed agonist compound so as to effect a viable obesity treatment regimen. Treatment/administration protocols depend upon the nature of the compound being administered as well as the clinical condition of the subject or patient. In the absence of additional information the skilled artisan would not have been able to use the undisclosed compound(s) for treatment without undue experimentation.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of obesity, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating obesity, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the method is drawn to the treatment of a particular disease of real world relevance. In addition, based upon the instant fact pattern, there is no reason to question the assertion that one could potentially treat obesity with agonists to the claimed R-receptor.

35 U.S.C. § 112, first paragraph: Written Description

This claim fails to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph for the reasons set forth with respect to claim 3. The claimed invention is drawn to a method of treatment that requires the use of an undisclosed agonist. In order to evidence possession of the claimed method, one would need to demonstrate possession of the claimed process steps which require the use of an undisclosed compound.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph for the reasons set forth with respect to claim 3. Given that there is no disclosure of any particular agonist and how to administer it, one skilled in the art would not have been able to have practiced the process steps recited in the claim without undue experimentation.

The claim fails to meet the requirements for the "how to use" prong of 35 U.S.C. § 112 for the reasons set forth with respect to claim 3.

5. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C. § 101. In the instant case, assaying the presence or absence of the receptor is useful in diagnostic methods relating to obesity and an antibody could be used in such assays.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one would have been able to used routine and well known methods to prepare an antibody to such a target.

This claim meets the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, since there were well established methods for using antibodies in detection assays.

Example 3

Outline of Specification:

The application describes the isolation of a protein (SEQ ID NO: 3) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application describes methods of screening for compounds that activate this receptor. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any particular biological or biochemical process in which this receptor is involved, except that its activation induces a cascade of second-messenger signals, similar to that of a G-protein coupled receptor.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims. In particular, there is a description of a method of identifying or screening for agonists of this receptor, i.e., compounds that activate the claimed receptor, wherein the activated state is detected when a cascade of second-messenger signals occurs. There is no doubt that the skilled artisan could use the claimed R-receptor to identify (find) agonists.

In addition, the application discloses three working examples wherein compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 3 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 3.

35 U.S.C. § 101: Utility

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim does not meet the utility requirement of 35 U.S.C. § 101. In this example, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-

receptor family of proteins. Assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. The fact that the claimed receptor mediates signals by widespread pathways such as those associated with G-coupled protein receptor fails to cure this problem without some indication of the particular process with which the receptor is associated.

The rejection might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity or that the as-filed specification would have been sufficient to provide the artisan with an indication of a real world use.

35 U.S.C. § 112, first paragraph: Written Description

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein sequence, the skilled artisan would have been able to have prepared the claimed protein.

However, this claim does <u>not</u> meet the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, because the disclosure does not teach a use that would meet the utility requirement of 35 U.S.C. § 101 (see comments below re: claim 2).

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

This claim would not meet the utility requirement of 35 U.S.C. § 101. As noted above in the comments regarding claim 1, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins. However, assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. In the case of the instant claim to a method of identifying an agonist, in the absence of an understanding of a specific and substantial use for the agonist, a method of identifying such would not comply with the requirements for utility.

The rejection might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity, or that there would be a specific and substantial use for the product identified by the claimed method.

35 U.S.C. § 112, first paragraph: Written Description

This method of identifying agonist compounds meets the requirement for an adequate written description as required by 35 U.S.C. § 112, first paragraph, because it is specifically noted that the specification teaches methods of screening for compounds that activate this receptor. That is, the activated state can be detected when a cascade of second-messenger signals occurs. Therefore, one skilled in the art would conclude that the applicant was in possession of such methods.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the requirements for "how to make" requirement of 35 U.S.C. § 112, first paragraph, since the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1.

However, the claim fails to meet the "how to use" requirement of 35 U.S.C. § 112, first paragraph, for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101.

3. An isolated and purified receptor agonist identified by the method of claim 2.

35 U.S.C. § 101: Utility

This claim would not meet the utility requirement of 35 U.S.C. § 101. As noted above in the comments regarding claim 1, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins. However, assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. In the case of the instant claim to an agonist identified by the method of claim 2, there is no

indication of the use to which the claimed agonist is to be put, therefore, the artisan would have to discover a use. Therefore, the claimed invention is not be supported by a substantial utility.

The rejection might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity, or that a specific and substantial purpose for agonizing such function would have been known to those of skill in the art.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to a genus of agonist(s) identified by the method of claim 2 and the specification discloses at least some examples of the structure of compounds within the scope of what is claimed. However, there is no evidence that there is any *per se* structure/function relationship between the disclosed agonist compounds and any others that might be found using the claimed method. Structural identifying characteristics of the genus members are not disclosed. Therefore, the claimed invention is not supported by an adequate written description.

The rejection might be overcome with a showing of objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Since the instant fact pattern fails to indicate that a representative number of structurally related compounds is disclosed, the artisan would not know the identity of any nondisclosed compound falling within the scope of the instant claim and consequently would not have know how to make it. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. A rejection indicating that the claimed invention is only enabled for how to make those compounds specifically disclosed would be appropriate.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed methods fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist of claim 3.
   (JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said

agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim does not meet the utility requirement of 35 U.S.C. § 101. The claimed invention is drawn to a method of treating an undisclosed disease. Since the fact pattern fails to establish what disease, if any, would be treatable by the agonist, the artisan would have no specific and substantial treatment to perform.

Objective evidence might overcome this rejection if it supported an assertion that one of ordinary skill in the art would recognize what disease(s) would have been able to have been treated with the claimed agonist.

35 U.S.C. § 112, first paragraph: Written Description

This method of treatment claim fails to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. There is insufficient descriptive support for the genus "agonist" as explained above. Further, the method requires treatment of an unspecified disease and no evidence indicates that a treatable disease was known to applicant. Therefore, the fact pattern indicates that the artisan was not in possession of the claimed method of use. In the absence of some understanding of the disease to be treated and which, if any, agonists could be used to treat said disease, the artisan would not have accepted that the applicant was in possession of the claimed method.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given that no treatable disease is disclosed nor any information as to how any particular undisclosed agonist would have been administered to treat any specific disease, the artisan would not have been able to have practiced the steps required by the claimed invention without undue experimentation.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed method fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph.

5. (EPO) Use of compound X for the manufacture of a medicament for treating a disease treatable by said compound.
   (USPTO) A method for treating a disease treatable by compound X comprising administering to a host in need thereof a therapeutically effective amount of compound X.

(JPO) Composition comprising compound X for use in treating a disease treatable by said compound, as an active ingredient.

This claim fails to meet the collective requirements of 35 U.S.C. §§ 101, 112, first paragraph, written description and enablement for the same reasons as set forth above in the analysis of claim 4, except that compound X itself is adequately described, and that one skilled in the art would be able to make compound X based on the disclosure.

6. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim does not meet the utility requirement of 35 U.S.C. § 101. Given that there is no utility for the claimed receptor, there would be no specific and substantial reason to detect it with the claimed antibody or to use the antibody in any other manner.

The rejection might be overcome by a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one would have been able to use routine and well known methods to prepare an antibody to such a target.

However, this claim does <u>not</u> meet the requirement for the "How to use" prong of 35 U.S.C. § 112, first paragraph, because the disclosure does not teach a use that would meet the utility requirement of 35 U.S.C. § 101.

<u>Example 4:</u>

<u>Outline of Specification:</u>

The application describes the isolation of a receptor (SEQ ID NO: 4) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims.

In addition, the application discloses three working examples wherein agonists of this receptor, i.e., compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

Furthermore, the pharmacological mechanism involved in the treatment or inhibition of obesity by the activation of this receptor is described theoretically in the specification.

In addition, *in vivo* test data confirms that at least compound X is able to activate this receptor when administered to a host animal and such administration results in a reduction in total body weight of an art recognized model for obesity.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 4 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 4.

35 U.S.C. § 101: Utility

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C.
§ 101. In the instant case, the presence or absence of the receptor is useful in diagnostic methods relating to obesity.

35 U.S.C. § 112, first paragraph: Written Description

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the "how to make" prong of the enablement requirement of 35 U.S.C. § 112, first paragraph. Given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. The claim meets the "how to use" prong of 35 U.S.C. § 112, first paragraph, since the receptor's presence or absence may be used in diagnostic methods relating to obesity.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
preparing a candidate compound,
contacting a cell which expresses said receptor on its surface with said candidate compound, and
determining whether said candidate compound activates the receptor of claim 1,
wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the instant fact pattern indicates that agonist compounds that, by definition, activate their cognate molecules, would be potentially useful for the treatment of obesity.

35 U.S.C. § 112, first paragraph: Written Description

This method of identifying agonist compounds meets the requirement for an adequate written description as required by 35 U.S.C. § 112, first paragraph, because it is specifically noted that the specification teaches methods of screening for compounds that activate this receptor. Therefore, the person skilled in the art would conclude that the applicant was in possession of such methods.

35 U.S.C. § 112, first paragraph: Enablement

This claim also meets the requirements for how to make and use the claimed method of identifying agonist compounds since the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1.

3. An isolated and purified receptor agonist identified by the method of claim 2.

35 U.S.C. § 101: Utility

The claimed receptor agonist meets the requirement for utility as set forth in 35 U.S.C. § 101 for reasons set forth above in the analysis of claims 1 and 2.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to a genus of agonist(s) identified by the method of claim 2 and the specification discloses at least some examples of the structure of compounds within the scope of what is claimed. Structural identifying characteristics of the agonist genus are not disclosed. There is no evidence that there is any *per se* structure/function relationship between the disclosed agonist compounds and any others that might be found using the claimed method. Therefore, the claimed invention is not supported by an adequate written description.

The rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make and use" prongs of 35 U.S.C. § 112, first paragraph for the full scope of what is claimed. Since the instant fact pattern fails to indicate that a representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and consequently would not have know how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. A rejection indicating that the claimed invention is only enabled for those compounds specifically disclosed would be appropriate.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating obesity wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the method is drawn to the treatment of a particular disease of real world relevance. In addition, based upon the instant fact pattern, there is no reason to question the assertion that one could potentially treat obesity with agonists to the claimed R-receptor.

35 U.S.C. § 112, first paragraph: Written Description

This method of treatment claim fails to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. There is insufficient descriptive support for the genus "agonist" as explained above. Further, the claimed invention is drawn to a method of treatment that requires the use of undisclosed agonists. In order to evidence

possession of the claimed method, one would need demonstrate possession of its process steps which require the use of undisclosed compounds.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make and use" prongs of 35 U.S.C. § 112, first paragraph for the full scope of what is claimed. Since the instant fact pattern fails to indicate that a representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and consequently would not have known how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. A rejection indicating that the claimed invention is only enabled for those compounds specifically disclosed would be appropriate.

5. (EPO) Use of compound X for the manufacture of a medicament for inhibiting obesity.
(USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of compound X.
(JPO) Composition comprising compound X for use in treating obesity, as an active ingredient.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the method is drawn to the treatment of a particular disease of real world relevance. In addition, based upon the instant fact pattern, there is no reason to question the assertion that one could potentially treat obesity with agonists to the claimed R-receptor.

35 U.S.C. § 112, first paragraph: Written Description

This method of treatment claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph, since the claimed invention is drawn to treating a disclosed disorder using a disclosed and adequately described agonist.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "How to make and use" prongs of 35 U.S.C. § 112, first paragraph since the claimed invention is drawn to treating a disclosed disorder using a disclosed agent.

6. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C.
§ 101. In the instant case, the presence of absence of the receptor is useful in diagnostic methods relating to obesity and an antibody could be used in such assays.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one would have been able to use routine and well known methods to prepare an antibody to such a target.

This claim meets the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, since there were well established methods for using antibodies in detection assays.