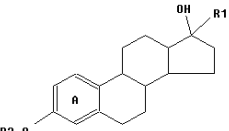
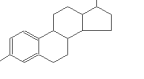
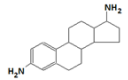
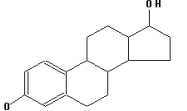
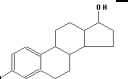
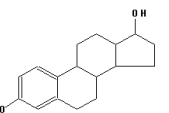
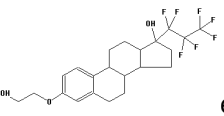
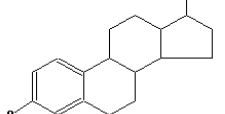


| PCT CH.I Stage     |   | SIPO  | EPO | JPO | USPTO | KIPO | COMMENTS SIPO | COMMENTS EPO | COMMENTS JPO | COMMENTS USPTO | COMMENTS KIPO |
|--------------------|---|---|-----|-----|-------|------|---------------|--------------|--------------|----------------|---------------|
| <b>EXAMPLE 1</b>   | <p>The application comprises one independent compound claim:<br/>The invention relates to a compound of Formula (I) and its use to inhibit estrogen receptor-alpha (ER). The compounds are useful in the treatment of estrogen related diseases. The treatment of breast cancer is the preferred embodiment.<br/>The object of the invention is to provide a compound for the prophylaxis or treatment of especially breast cancer development (problem X).<br/><b>Independent claim 1:</b></p>  <p>A compound of Formula (I),<br/>or a pharmaceutically acceptable salt thereof, wherein R1 is hydrogen or is a group selected from fully or partially fluorinated C1-6alkyl and a residue of a natural amino acid; R2 is hydrogen, acyl or hydroxyC1-6alkyl; and wherein ring A is optionally substituted with up to 3 substituents individually selected from methyl and halogen.</p>   |   |     |     |       |      |               |              |              |                |               |
| <b>Scenario 1A</b> | The compound of Formula (I) with an aromatic ring A and having the combination of substituent groups R1 and R2 is not disclosed in the prior art. The compound of Formula I is novel.   |   |     |     |       |      |               |              |              |                |               |
| <b>QUESTION 1</b>  | Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?  | U   | U   | U   | U     | U    |               |              |              |                |               |
| <b>QUESTION 2</b>  | Would your office raise an objection of non-unity at this stage (R=raise / N= not raise)  | N   | N   | N   | NR    | N    |               |              |              |                |               |
| <b>QUESTION 3</b>  | Would your office request additional fees (Y/N)   | N   | N   | N   | N     | N    |               |              |              |                |               |
| <b>Scenario 1B</b> | <p>D1 discloses the following compound B:<br/>which is a starting material for producing a steroid derivative wherein both OH substituents are replaced by amino groups.</p>  <p>The final compound C inhibits estrogen receptor-alpha (ER) and solves the problem X of prophylaxis or treatment of especially breast cancer development. The structural features which are common for all alternatives embraced by Formula (I) are a tetracyclic steroid having an aromatic ring A and bearing 2 oxygen substituents.</p>  <p>The compound of Formula (I) is not novel because a specific intermediate compound B falls under the definition of the general formula.</p> <p>The final compound C of D1 solves problem X, but does not disclose the common structural features of Formula (I).</p>  |   |     |     |       |      |               |              |              |                |               |
| <b>QUESTION 1</b>  | Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?  | NU  | U   | U   | NU    | U    |               |              |              |                |               |
| <b>QUESTION 2</b>  | Would your office raise an objection of non-unity at this stage (R=raise / N= not raise)  | (1) N (if there are embodiments when R1 is a residue of a natural acid solving the same problem;<br>(2) R (if there are no embodiments when R1 is a residue of a natural acid solving the same problem) | N   | N   | R     | N    |               |              |              |                |               |
| <b>QUESTION 3</b>  | Would your office request additional fees (Y/N)   | (1) N;<br>(2) Y   | N   | N   | Y     | N    |               |              |              |                |               |
| <b>Scenario 1C</b> | <p>D1 discloses the compound B,<br/>which falls under the options for R1 and R2 in Formula (I).</p>  <p>The product solves the problem (Y) of how to avoid hair loss. The structural features which are common for all alternatives embraced by Formula (I) are a tetracyclic steroid having an aromatic ring A and bearing 2 oxygen substituents.</p> <p>The compound of Formula (I) is not novel because compound B falls under the definition of the general formula.</p> <p>Problems X and Y are different and unrelated.</p>   |   |     |     |       |      |               |              |              |                |               |
| <b>QUESTION 1</b>  | Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?  | U   | U   | U   | NU    | U    |               |              |              |                |               |
| <b>QUESTION 2</b>  | Would your office raise an objection of non-unity at this stage (R=raise / N= not raise)  | N   | N   | N   | R     | N    |               |              |              |                |               |
| <b>QUESTION 3</b>  | Would your office request additional fees (Y/N)   | N   | N   | N   | Y     | N    |               |              |              |                |               |

|                           |   |   |           |           |           |           |  |  |  |  |  |  |  |  |  |  |  |
|---------------------------|---|---|-----------|-----------|-----------|-----------|--|--|--|--|--|--|--|--|--|--|--|
| <p><b>Scenario 1D</b></p> | <p>D1 discloses the following compound C,</p>  <p>which falls under the options for R1 and R2 in Formula (I) molecule BRCA1-mimetic.</p> <p>D1 discloses that BRCA1 protein binds to estrogen receptor-alpha (ER) and functions to regulate ER activity. Mutations of BRCA1 account for half of all hereditary breast cancers. Compound C was identified as a potent inhibitor of ER.</p> <p>The skilled person would conclude that this compound also solves the problem X. The structural features which are common for all alternatives embraced by Formula (I) are a tetracyclic steroid having an aromatic ring A and bearing 2 oxygen substituents.</p> <p>The compound of Formula (I) is not novel (a specific compound C falls under the definition of the general formula).</p> <p>Compound C also solves the same problem X as the compound of Formula (I).</p> <p>The alternative groups in R1 (hydrogen, fully or partially fluorinated C1-6alkyl, natural amino acid) represent alternative and technically unrelated solutions to problem X</p>  |   |           |           |           |           |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>QUESTION 1</b></p>  | <p>Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?</p>   | <p>NU</p>   | <p>NU</p> | <p>NU</p> | <p>NU</p> | <p>NU</p> |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>QUESTION 2</b></p>  | <p>Would your office raise an objection of non-unity at this stage (R=raise / N= not raise)</p>   | <p>1)N (if there are embodiments when R1 is a residue of a natural acid solving the same problem;<br/>2)R (if there are no embodiments when R1 is a residue of a natural acid solving the same problem)</p> | <p>R</p>  | <p>R</p>  | <p>R</p>  | <p>R</p>  |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>QUESTION 3</b></p>  | <p>Would your office request additional fees (Y/N)</p>  | <p>(1)N;<br/>(2) Y</p>  | <p>Y</p>  | <p>Y</p>  | <p>Y</p>  | <p>Y</p>  |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>EXAMPLE 2</b></p>   | <p><b>The application comprises three independent claims:</b> Claim 1: Use of compound X for the manufacture of a medicament for treating ovarian cancer</p> <p>Claim 2: Use of compound X for the manufacture of a medicament for treating lung cancer</p> <p>Claim 3: Use of compound X for the manufacture of a cosmetic product for treating hair loss</p>  |   |           |           |           |           |  |  |  |  |  |  |  |  |  | <p>Example 2 involves "Use" claims. Use claims may not be interpreted/examined consistently across different ISAs (and IPEAs) due to variances in national practices. Furthermore, certain DO/EOs may consider "use" claims to be improper process claims which lack clarity and constitute excluded subject matter. See International Search and Preliminary Examination Guidelines paragraph A5.21.</p> <p>If the intent is to move forward with this example, perhaps including</p> |  |
| <p><b>Scenario 2A</b></p> | <p>D1 discloses compound X.<br/>There is no indication of its medical or cosmetic use<br/>Compound X is known<br/>Use of compound X for manufacture of a medicament or cosmetic product is not known</p>  |   |           |           |           |           |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>QUESTION 1</b></p>  | <p>Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?</p>   | <p>NU</p>   | <p>U</p>  | <p>U</p>  | <p>NU</p> | <p>NU</p> |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>QUESTION 2</b></p>  | <p>Would your office raise an objection of non-unity at this stage (R=raise / N= not raise)</p>   | <p>R</p>  | <p>N</p>  | <p>N</p>  | <p>R</p>  | <p>R</p>  |  |  |  |  |  |  |  |  |  |  |  |
| <p><b>QUESTION 3</b></p>  | <p>Would your office request additional fees (Y/N)</p>  | <p>Y</p>  | <p>N</p>  | <p>N</p>  | <p>Y</p>  | <p>Y</p>  |  |  |  |  |  |  |  |  |  |  |  |

|                    |   |    |    |    |    |    |  |  |  |  |  |  |
|--------------------|---|----|----|----|----|----|--|--|--|--|--|--|
| <b>Scenario 2B</b> | D1 discloses compound X and its use for treating eating disorders such as bulimia, anorexia, etc. Compound X is known.<br>Use of compound X for manufacture of a medicament is known<br>The medicament of D1 is unrelated to the medicaments of claims 1 or 2 |    |    |    |    |    |  |  |  |  |  |  |
| <b>QUESTION 1</b>  | Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?  | NU | NU | NU | NU | NU |  |  |  |  |  |  |
| <b>QUESTION 2</b>  | Would your office raise an objection of non-unity at this stage<br>(R=raise / N= not raise)   | R  | R  | R  | R  | R  |  |  |  |  |  |  |
| <b>QUESTION 3</b>  | Would your office request additional fees (Y/N)   | Y  | Y  | Y  | Y  | Y  |  |  |  |  |  |  |
| <b>Scenario 2C</b> | D1 discloses compound X and its use for treating brain cancer. Compound X is known<br>Use of compound X for manufacture of a medicament for a specific cancer is known  |    |    |    |    |    |  |  |  |  |  |  |
| <b>QUESTION 1</b>  | Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?  | NU | NU | NU | NU | NU |  |  |  |  |  |  |
| <b>QUESTION 2</b>  | Would your office raise an objection of non-unity at this stage<br>(R=raise / N= not raise)   | R  | R  | R  | R  | R  |  |  |  |  |  |  |
| <b>QUESTION 3</b>  | Would your office request additional fees (Y/N)   | Y  | Y  | Y  | Y  | Y  |  |  |  |  |  |  |