**EXAMPLE 1**

The application comprises one independent compound claim:

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.

Independent claim 1:

A compound of Formula (I),
or a pharmaceutically acceptable salt thereof, wherein R1 is hydrogen or is a group selected from fully or partially fluorinated C1-C10-alkyl and a residue of a natural amino acid; R2 is hydrogen, acyl or hydroxyC1-6-alkyl; and wherein ring A is optionally substituted with up to 3 substituents individually selected from methyl and halogen.

---

**Scenario 1A**

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.

**QUESTION 1** Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?

**QUESTION 2** Would your office raise an objection of non-unity at this stage (R=raise / N=not raise)?

**QUESTION 3** Would your office request additional fees (Y/N)?

---

**Scenario 1B**

D1 discloses the following compound B, which is a starting material for producing a steroid derivative wherein both OH substituents are replaced by amino groups.

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.

**QUESTION 1** Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?

**QUESTION 2** Would your office raise an objection of non-unity at this stage (R=raise / N=not raise)?

**QUESTION 3** Would your office request additional fees (Y/N)?

---

**Scenario 1C**

D1 discloses the compound B, which falls under the options for R1 and R2 in Formula (I).

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.

**QUESTION 1** Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?

**QUESTION 2** Would your office raise an objection of non-unity at this stage (R=raise / N=not raise)?

**QUESTION 3** Would your office request additional fees (Y/N)?
**Scenario 1D**

D1 discloses the following compound C, which falls under the options for R1 and R2 in Formula (I), as a small-molecule BRCA1-mimetic.

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.

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 tetra cyclic steroid having an aromatic ring A and bearing 2 oxygen substituents.

The compound of Formula (I) is not novel (a specific compound C falls under the definition of the general formula).

Compound C also solves the same problem X as the compound of Formula (I).

The alternative groups in R1 (hydrogen, fully or partially fluorinated C1-6 alkyl, natural amino acid) represent alternative and technically unrelated solutions to problem X.

---

**Example 2**

The application comprises three independent claims:

- Claim 1: Use of compound X for the manufacture of a medicament for treating ovarian cancer
- Claim 2: Use of compound X for the manufacture of a medicament for treating lung cancer
- Claim 3: Use of compound X for the manufacture of a cosmetic product for treating hair loss

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 XOs/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.

If the intent is to move forward with this example, exclude claim 3.

---

**Scenario 2A**

- D1 disclose compound X.
- There is no indication of its medical or cosmetic use.
- Compound X is known.
- Use of compound X for manufacture of a medicament or cosmetic product is not known.

**QUESTION 1**

Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?

- NU U U U NU

**QUESTION 2**

Would your office raise an objection of non-unity at this stage (R = raise / N = not raise)?

- R R R R

**QUESTION 3**

Would your office request additional fees (Y = yes / N = no)?

- Y Y N Y
### Scenario 2B

D1 discloses compound X and its use for treating eating disorders such as bulimia, anorexia, etc. Compound X is known. Use of compound X for manufacture of a medicament is known. The medicament of D1 is unrelated to the medicaments of claims 1 or 2.

<table>
<thead>
<tr>
<th>QUESTION 1</th>
<th>Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUESTION 2</th>
<th>Would your office raise an objection of non-unity at this stage (R/No not raise)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUESTION 3</th>
<th>Would your office request additional fees (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
</tr>
</tbody>
</table>

### Scenario 2C

D1 discloses compound X and its use for treating brain cancer. Compound X is known. Use of compound X for manufacture of a medicament for a specific cancer is known.

<table>
<thead>
<tr>
<th>QUESTION 1</th>
<th>Would your office consider these claims to be Unitary (U) or Non-Unitary (NU)?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUESTION 2</th>
<th>Would your office raise an objection of non-unity at this stage (R/No not raise)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUESTION 3</th>
<th>Would your office request additional fees (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
</tr>
</tbody>
</table>