Disclaimer Practice at the EPO

The European Patent Office (EPO) uses the term “disclaimer” to refer to a negative feature in a claim of a patent application. Negative features are those which exclude certain subject matter from the scope of protection. While a positive feature in a claim may for instance take the form “wherein the composition comprises X”, a disclaimer would take the form “wherein the composition does not comprise X”.

Disclaimers can be a useful means of avoiding prior art which cannot easily be overcome by introduction of a positive limitation. However, it is not always straightforward to determine whether a disclaimer can be added to a claim without contravening the prohibition in Article 123(2) EPC against amendments which are not properly based on the disclosure in the application as filed.

There are three circumstances under which the introduction of a disclaimer will be acceptable under Article 123(2) EPC. These are:

i. where the negative feature excluding specific subject matter is based on language set out in the application as originally filed;

ii. where the disclaimer excludes subject matter which is disclosed only in positive terms in the application as filed and consideration of the overall teaching of the application as filed leads to the conclusion that the subject-matter remaining in the claim is “directly and unambiguously disclosed” in the application as filed; and

iii. where the disclaimer which excludes subject matter which is not disclosed in either positive or negative terms in the application as filed but which operates only (a) to avoid the disclosure of novelty-only prior art citeable under Article 54(3) EPC, (b) to avoid accidental anticipation by prior art which is technically unrelated to the claimed invention or (c) to disclaim subject-matter that is excluded from patentability for non-technical reasons (such as a method of medical treatment).

These categories of disclaimer are discussed in more detail below.

Category (i): Disclaimers based on language present in the application as filed

The general rule governing amendments to claims of a European patent or patent application is
that features can be added without contravening Article 123(2) EPC if there is direct and unambiguous basis in the application as originally filed for the language used. Thus, the introduction of a negative feature excluding specific subject matter will not contravene Article 123(2) EPC if it is based on language set out in the application as originally filed.

The application as originally filed will of course only contain basis for a negative limitation if the applicant was able to foresee when drafting the application the need to exclude the subject matter at issue. That may be the case if there is relevant disclosure in the applicant’s own earlier filed, but unpublished, patent applications. Such applications may be citeable only for the assessment of novelty, and the prior art disclosure may conveniently be “carved out” of the claims by disclaimer, without having to introduce a broader positive limitation.

More often, however, applicants do not have the benefit of being aware of all relevant prior art when drafting an application. For this reason, it is relatively unusual for an application to contain explicit basis for the negative language of a disclaimer.

**Category (ii): “Disclosed” disclaimers**

Disclaimers which exclude subject matter which is disclosed only in positive terms in the application as filed are identified in the case law of the Boards of Appeal as “disclosed” disclaimers.

The circumstances under which a disclosed disclaimer is permitted under Article 123(2) EPC is discussed in detail by the EPO’s Enlarged Board of Appeal in G2/10. That decision arose due to a conflict in the Board of Appeal case law. For example, in decision T1102/00 it was suggested that subject-matter could be excluded only if it was expressly disclosed as subject-matter to be excluded from protection (i.e. if it is a “category (i)” disclaimer as discussed above). On the other hand T1107/06 suggested a more liberal approach, whereby it should be permissible to disclaim any subject matter disclosed in the application as filed in positive terms (for example as a preferred embodiment of the invention).

The Enlarged Board rejected the two extreme positions. Thus, it was held that Article 123(2) EPC does not require an absolute bar on the introduction of a disclosed disclaimer. However, the Board also held that a disclosed disclaimer will not always be allowable.

The Enlarged Board held that a disclosed disclaimer should not be permitted if the subject-matter remaining in the claim after the introduction of the disclaimer is not “directly and unambiguously disclosed”. Further, the Board ruled that “[d]etermining whether or not that is the case requires a technical assessment of the overall technical circumstances of the individual case under consideration, taking into account the nature and extent of the disclosure in the application as filed, the nature and extent of the disclaimed subject-matter and its relationship with the subject-matter remaining in the claim after the amendment”.

It is therefore clear that assessment of a disclosed disclaimer must have regard to the specific facts of the application at issue. The detailed reasoning in G2/10 is complex and it is not always
fully clear how the required “technical assessment” will be implemented by the Examining Divisions, Opposition Divisions and Boards of Appeal at the EPO. Nonetheless, the following general observations do emerge.

- Where a generally worded claim embraces many specific embodiments of an invention, and the disclosed disclaimer is based on a single such embodiment (e.g. the subject-matter of one of a number of working Examples), this is likely to be allowable. That is because the subject-matter remaining in the amended claim does not contain new “technical information” or result in the “singling out” of other embodiments that were not specifically disclosed in the original application.

- On the other hand, a disclosed disclaimer will not be allowed if it results in an amended claim that has special technical characteristics not disclosed in the original application or in which particular combinations of features have been singled out in a manner not disclosed in the original application. That is because the subject-matter in the amended claim would then contain new “technical information” compared with the originally filed application.

The practical examples set out in the attached Annex may assist with understanding the nature of the technical assessment envisaged in G2/10.

**Category (iii): “Undisclosed” disclaimers**

Disclaimers which exclude subject matter which is not disclosed at all in the application as filed are identified in the case law of the Boards of Appeal as “undisclosed” disclaimers. In G1/03, the EPO’s Enlarged Board of Appeal considered the circumstances in which an undisclosed disclaimer might be allowable under Article 123(2) EPC. In this decision, the following exceptional circumstances were outlined:

1. to restore novelty over disclosure in an earlier unpublished European application citable for novelty only in accordance with Article 54(3) EPC;
2. to restore novelty over an “accidental anticipation” contained in a prior art document, an anticipation being “accidental” if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention; and
3. to disclaim subject-matter that is excluded from patentability for non-technical reasons (e.g. a method of medical treatment).

The purpose of the first two of these exceptions is to assist applicants in cases where they could not reasonably have been aware of the prior art disclosure and may have no positive amendments available to them. However, the Enlarged Board also added the following three conditions:

i. the disclaimer should not remove more than is necessary either to restore novelty or to disclaim subject-matter excluded from patentability for non-technical reasons;
ii. a disclaimer which is or becomes relevant for the assessment of inventive step or sufficiency of disclosure adds subject-matter contrary to Article 123(2) EPC; and

iii. claim containing a disclaimer must meet the requirements of clarity and conciseness of Article 84 EPC.

These additional conditions must be carefully considered when including an undisclosed disclaimer. In particular, it can be difficult to determine precisely what is disclosed in the prior art and thus what the exact scope of the disclaimer should be. If too broad an undisclosed disclaimer is introduced during prosecution, it cannot be narrowed after grant. That is because making the disclaimer narrower will represent an unallowable broadening of the claim under Article 123(3) EPC. For this reason, it is advisable to introduce the narrowest undisclosed disclaimer possible under the circumstances.

Following G2/10 (discussed above), a conflict arose in the Board of Appeal case law as to whether the requirements of that decision applied to undisclosed disclaimers as well as to disclosed disclaimers. In T0347/14, the Technical Board of Appeal pointed out that if the G2/10 requirements apply to undisclosed disclaimers, undisclosed disclaimers would effectively be prohibited. That is because it is difficult to see how the subject matter remaining in the claim after the introduction of an undisclosed disclaimer could be “directly and unambiguously disclosed” in the application as filed. The Technical Board of Appeal thus referred the issue of the allowability of undisclosed disclaimers to the Enlarged Board of Appeal for further consideration.

The Enlarged Board of Appeal considered the possible conflict between G1/03 and G2/10 in decision G1/16. G1/16 confirmed that when assessing whether an undisclosed disclaimer is allowable under Article 123(2) EPC it is necessary only to apply the criteria of G1/03. The conditions of G2/10 do not have to be met by undisclosed disclaimers.

Examples of undisclosed disclaimers which do and do not meet the requirements of G1/03 are given in the Annex to this briefing.

**Annex: Practical Examples Involving Assessment of Disclaimers**

<table>
<thead>
<tr>
<th>Claim</th>
<th>Desired disclaimer</th>
<th>Disclosure of disclaimer</th>
<th>Allowable?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical compound defined using general formula</td>
<td>Single compound falling within scope of general formula</td>
<td>As an embodiment of the invention in the application</td>
<td>Likely to be allowable as a G2/10 disclosed disclaimer, particularly if the disclaimed compound is only one of many compounds specifically disclosed in the application as filed (no new “technical information”).</td>
</tr>
<tr>
<td>Chemical compound defined using general formula</td>
<td>Single compound falling within scope of general formula</td>
<td>No disclosure in application</td>
<td>No - undisclosed disclaimer not allowable unless an exceptional circumstance of G1/03 applies.</td>
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</tr>
<tr>
<td>Chemical compound defined using general formula</td>
<td>Single compound falling within scope of general formula</td>
<td>Disclosed in a prior art document published between the priority date and the filing date</td>
<td>Assuming the priority claim is valid, the prior art document will be citeable under Art 54(3) EPC for novelty only. The disclaimer should therefore be allowable as a G1/03 undisclosed disclaimer.</td>
</tr>
<tr>
<td>Chemical compound defined using general formula</td>
<td>Single compound falling within scope of general formula</td>
<td>Disclosed in a patent application filed in the same name as the applicant and which was published between the priority date and the filing date</td>
<td>This situation is similar to that set out above. However, if the relevant prior art is a patent application filed in the same name as the applicant, the priority claim will be invalid, insofar as the claims embrace the single compound at issue, because the prior art patent application will be the “first application” for the relevant subject matter under Art 87 EPC. Thus, although the prior art may still effectively be a novelty-only citation, it is formally citeable under Art 54(2) rather than Art 54(3) EPC, and a G1/03 undisclosed disclaimer may not therefore be available.</td>
</tr>
<tr>
<td>Chemical compound having specified general formula or a salt thereof</td>
<td>Single compound excluded from the scope of the general formula.</td>
<td>Specific compound which is the subject of the disclaimer disclosed by name in novelty-only prior art document citeable under Article 54(3) EPC</td>
<td>No - undisclosed disclaimer not allowable under G1/03. By excluding the specific compound from the scope of the general formula, the disclaimer excludes both the compound and salts thereof. The prior art disclosed only the compound, and the disclaimer therefore removes more than is necessary to restore novelty. Note that if the Examiner does not notice this issue, and the patent is granted with a disclaimer along these lines, it would not be possible to correct the disclaimer after grant so that it properly excludes only the specific compound disclosed in the prior art. That would extend the scope of protection, contrary to Art 123(3) EPC</td>
</tr>
<tr>
<td>Chemical compound defined using general formula, for use in treating cancer</td>
<td>Single compound falling within scope of general formula</td>
<td>Disclosed in a prior art document as a dye compound</td>
<td>Likely to be allowable as a G1/03 undisclosed disclaimer against an “accidental anticipation”.</td>
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<tr>
<td>Chemical compound defined using general formula, for use in treating cancer</td>
<td>Single compound falling within scope of general formula</td>
<td>Disclosed in a prior art document as an analgesic</td>
<td>No - not an “accidental anticipation” according to current Board of Appeal case law (e.g. T 1911/08) and so not an acceptable G1/03 undisclosed disclaimer.</td>
</tr>
<tr>
<td>Chemical compound defined using general formula, for use in treating cancer</td>
<td>Single compound falling within scope of general formula</td>
<td>Disclosed in a prior art document as an analgesic; also disclosed as an embodiment of the invention in the application</td>
<td>May be allowable as a G2/10 disclosed disclaimer.</td>
</tr>
<tr>
<td>Method of reducing weight of a human subject</td>
<td>Therapeutic (i.e., non-cosmetic) method of reducing weight of a human subject</td>
<td>No disclosure in application</td>
<td>Likely to be allowable as G1/03 undisclosed disclaimer as disclaimer of “therapeutic method” is for purely non-technical reasons.</td>
</tr>
<tr>
<td>Chemical compound where substituent A is methyl, ethyl or propyl and substituent B is methyl, ethyl or propyl</td>
<td>Chemical compound where at least one of substituents A and B is either ethyl or propyl</td>
<td>As an embodiment of the invention in the application</td>
<td>Unlikely to be allowable under G2/10, because disclaimer results in “singling out” of the compound where A is methyl and B is methyl.</td>
</tr>
<tr>
<td>Chemical compound where substituent A is methyl, ethyl or propyl and substituent B is methyl, ethyl or propyl</td>
<td>Chemical compound where at least one of substituents A and B is either ethyl or propyl</td>
<td>Disclosed in a novelty-only prior art document citable under Article 54(3) EPC</td>
<td>Likely to be allowable as a G1/03 undisclosed disclaimer.</td>
</tr>
</tbody>
</table>

1 Article 123(2) EPC prohibits amendments that introduce new subject-matter to an application after filing. This provision is interpreted strictly by the EPO.

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