AMENDMENTS BEFORE THE EUROPEAN PATENT OFFICE

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The possibility of amending a patent application or a patent has been an issue largely discussed during the Travaux Préparatoires prior to the creation of the first version of the European Patent Convention (EPC) in 1973.

At this time, it was decided to enshrine in the Convention the possibility of amending the European patent application as a right available to any applicant. The European Patent Convention in the 1973 first version thus stated in Article 123(1) that “an applicant shall be allowed at least one opportunity of amending the description, claims and drawings of his own volition”.

This principle was reaffirmed during the revision of the European Patent Convention in 2000, where Article 123(1), which was by now in force, states similarly that “the applicant shall be given at least one opportunity to amend the application of his own volition”.

On the other hand, this right to amend the patent application needs to be limited to preserve the rights of third-parties so that they can predict what possible amendments could be made by the applicant based on the patent application which has been filed. A safeguard has thus been provided in the European Patent Convention through Article 123(2) that states “The European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed”.

This paper aims at explaining how the safeguard provided by Article 123(2) EPC is applied at the European Patent Office (EPO), providing examples of common amendments cases that could occur, and reviewing if there are other provisions in the European Patent Convention that further limit the possibility to amend the patent application or patent.
Spirit and basic principles of Article 123(2) EPC

The Enlarged Board of Appeal of the EPO indicated in its decision G1/93 what the main goal of the Article 123(2) EPC safeguard was, stating that the underlying idea of this provision is that an applicant shall not be allowed to improve his position by adding subject-matter not disclosed in the application as filed.

The Enlarged Board of Appeal considered this was unacceptable as it would otherwise give the applicant an unwarranted advantage and could be damaging to the legal security of third parties that rely on the content of the original application.

It is thus necessary to know what is considered as the “application as filed” and how to assess whether the subject-matter is disclosed in this source of information defined by the “application as filed”.

Perimeter of the “application as filed”

The “application as filed”, which is used as a reference to determine whether or not any subject-matter was disclosed by the applicant, obviously comprises the description, the claims, and the drawings, as they were on the date of filing. In particular, if the patent application has been filed without any claim, as is now possible, any later filed set of claims will not be part of the “application as filed” for the purpose of assessing the allowability of amendments.

Contrary to what might be imagined, the abstract is not considered to be a part of the “application as filed”, nor is the title of the application, as seen in the Board of Appeal decision T246/86. Similarly the Board of Appeal indicated in its decision T260/85 that the content of the priority document(s) is not a part of the “application as filed”.

What is taken into consideration in the “application as filed” includes the explicit disclosure but also any implicit disclosure, i.e. any disclosure that the skilled person would consider as necessarily contained in the patent application as a whole when reading what is explicitly mentioned, on the basis of his general knowledge.

The features which are disclosed in the description by mere reference to a document which is said to be “incorporated by reference” are not usually considered to be part of the “application as filed”. The conditions for the incorporation of features by reference to another document in a patent application are very strict in Europe and rarely fulfilled, meaning that examiners often request cancellation of the incorporation by reference.
As established by the Board of Appeal in its decision T689/90, incorporating information by reference is permissible only if the description of the application as filed leaves a skilled reader in no doubt that protection is or may be sought for specific limited features that are only disclosed in the reference document. To be acceptable, such features must

- contribute to achieving the technical aim of the invention and thus be comprised in the solution of the underlying technical problem of the invention;

- implicitly, clearly belong to the description of the invention contained in the application as filed; and

- be precisely defined and identifiable within the overall technical information in the reference document.

In principle, incorporation by reference of an entire document, without indication of the specific features to be incorporated will not be accepted. Put differently, should the incorporation of a document by reference be accepted, it will always be limited to the specific features identified for incorporation.

Assessment of the disclosure within the “application as filed”

The “gold standard” for assessing what has been disclosed within the “application as filed” for the purpose of amending the application is given by the Enlarged Board of Appeal in its decision G2/10 confirming the principles put forward in decisions G3/89 and G11/91.

In this decision, the Enlarged Board of Appeal indicates that “any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Article 123(2) EPC and can therefore, irrespective of the context of the amendment made, only be made within the limits of what skilled person would derive directly and unambiguously, using common general knowledge” (emphasis added).

As mentioned in decision T667/08 of the Board of Appeal, there is no need for literal support for an amendment to be considered as part of the subject matter of the “application as filed”.

Users of the European patent system may have had the impression that European examiners used a more restrictive assessment than the principle highlighted in G2/10. To avoid such restrictive approach, the Guidelines for Examination at the EPO were amended at the end of
2013 to specifically indicate that “literal support is, however, not required by the wording of Art. 123(2)”, (see part H-IV-2.3).

The common general knowledge of the skilled person must be taken into account when deciding what is clearly and unambiguously disclosed, which confirms that the disclosure of the application as filed is not limited to the explicit disclosure. Indeed, any disclosure implied by the explicit disclosure can be used for amending the application, provided that this implicit disclosure is a clear and unambiguous consequence of what is explicitly disclosed. It has to be noted that the common general knowledge of the skilled person is assessed at the date of filing of the application as filed.

This standard to assess what subject-matter has been effectively disclosed in the “application as filed” thus enables the elaboration of broader amendments in a sense that they are not strictly limited to what is explicitly disclosed.

It is however also very clear that the “application as filed” should not be seen as a reservoir where the applicant can pick and choose several features and combine them in any possible way. The Board of Appeal has indeed affirmed several times that it was not acceptable to select features pertaining to separate embodiments and combine them in order to artificially create another particular embodiment, unless the skilled person might seriously contemplate such combination of features based on the disclosure and/or its common general knowledge.

To ease the application of the above mentioned “gold standard”, the Enlarged Board of Appeal also put forward a so-called disclosure test in its decision G2/10. According to this test, an amendment made to the application would be acceptable provided that - after the amendment - the skilled person, with his general knowledge, is not presented with new technical information.

The above principles might appear to be a bit subjective, leading to antinomic situations where the examiners have a strict application of the general concept, whereas the Applicants rely on a broad construction of the “application as filed”.

To help both examiners and applicants, the Guidelines for Examination at the EPO have been clarified again in late 2014, where it has been specified in part H-IV-2.2 that “when assessing the conformity of the amended claims to the requirements of Art. 123(2), the focus should be placed on what is really disclosed to the skilled person by the documents as filed as directed to a technical audience. In particular, the examiner should avoid disproportionally focusing on the structure of the claims as filed to the detriment of the subject-matter that
the skilled person would directly and unambiguously derive from the application as a whole”.

The Case Law of the Boards of Appeal has also enabled the establishment over time of some tests and guidelines to help assessing the allowability of amendments in specific situations. We will now review those specific situations and applicable tests, illustrated with particular examples.

- Specific cases of amendments and corresponding assessment guide

There are several ways to amend an application, in particular to amend the claims, using the content of the “application as filed”. Even though it is not exhaustive, the EPO has tried to categorize different types of amendments with corresponding guidelines in order to help assess their acceptability with regard to the provision of Article 123(2) EPC. Below is a presentation of the main amendment possibilities.

- Replacement or removal of a feature

One type of amendment consists in removing a feature from a claim, or replacing one feature with another feature, which is similar to the removal of a first feature and addition of a second feature.

Assessment of the allowability of such type of amendment is made by using the so-called “Essentiality test” given in part H-V-3.1 of the Guidelines for Examination at the EPO (emphasis added):

The replacement or removal of a feature from a claim does not violate Art. 123(2) if the skilled person would directly and unambiguously recognise that:

1. the feature was not explained as essential in the disclosure;
2. the feature is not, as such, indispensable for the function of the invention in the light of the technical problem the invention serves to solve; and
3. the replacement or removal requires no real modification of other features to compensate for the change.

In case of a replacement by another feature, the replacing feature must of course find support in the original application documents, so as not to contravene Art. 123(2).
The three conditions (i), (ii) and (iii) stated above are cumulative and all of them need to be fulfilled so that the replacement or removal of a feature will be accepted.

For illustrative purpose of this type of amendment, we refer to the decision T207/10 of the Board of Appeal in the opposition against European patent EP 1 549 706 B1. Below is a comparison between some of the claims as filed and the main claim as granted for the corresponding patent (emphasis added).

### Claims 1 and 8 as filed

1. A coating having a thickness of from 5 to 25 μm, comprising a high-molecular-weight organic material and from 5 to 9 g/m² coloured pigments, wherein, based on the total amount of coloured pigments,
   (a) from 30 to 90 % by weight of [...] and
   (b) from 10 to 70 % by weight of [...] , are present.
8. A surface-coating composition comprising from 5 to 15 % by weight of [...], based on the total non-volatile content, wherein, based on the total amount of coloured pigments,
   (a) from 30 to 90 % by weight of [...] and
   (b) from 10 to 70 % by weight of [...] , are present.

In this example, the feature regarding the coating pigment weight (“5 to 9 g/m² of coloured pigment”) had been deleted from the claim while it was always presented in the description as being essential to solve the identified technical problem.

The Board of Appeal has thus decided that the removal of the coating pigment weight contravened the provisions of Article 123(2) EPC due to the fact that this feature was presented as essential and because there was no feature in the granted claim which could be seen as an equivalent, alternative definition of the coating pigment weight.
In particular, this feature of the coating pigment weight (in g/m²) had been replaced in claim 1 (directed to a dried coating) by a feature regarding the percentage by weight of pigment based on the total non-volatile content. However such feature was only presented in respect to the surface coating composition, and there was no indication that the deleted coating pigment weight feature of the dried coating was necessarily obtained based on such a percentage by weight of pigment. This was another ground for the Board of Appeal to consider that claim 1 as granted contravened the provisions of Article 123(2) EPC.

○ Inclusion of additional features

As mentioned above, the inclusion of additional features, in particular in the claims, can raise problems if the newly claimed combination of features cannot be derived from the “application as filed”.

Assessment of the allowability of such type of amendment is made by using the so-called “Novelty test” given in part H-V-3.2 of the Guidelines for Examination at the EPO (emphasis added):

A claim may be limited by inclusion of additional features, provided the resulting combination was originally disclosed and does not relate to an invention which was not searched, for example:

a. from dependent claims, which were dependent on the claim to be limited
b. from the description e.g. the examples
c. from drawings
d. arising from the conversion of an independent claim to a dependent claim.

As will be apparent from the illustrative example below, it is essential to bear in mind that the features presented as alternatives in the application as filed, with no suggestions of any combination, shall not be then allowed to be combined.

For illustrative purpose, we refer to the decision T2361/10 of the Board of Appeal in the opposition against European patent EP 1 432 369 B1. Below is a comparison between some of the claims as filed and some claims as granted for the corresponding patent (emphasis added).
2. A tissue connecting device for use with an elongate delivery device on tissue at a target site, the device comprising: an elongate member 10 deliverable to the target site via the elongate delivery device 20, said elongate member [...] wherein [...].

15. The device of claim 2 further comprising at least one suture coupled to the elongate member.

26. The device of claim 2 wherein said delivery device comprises a straightening mandrel.

27. The device of claim 2 wherein said elongate member contains a lumen therein for engaging a straightening mandrel.

28. The device of claim 2 wherein said delivery device comprises a catheter.

Claims 25 and 26 have been challenged in Opposition for contravening the provisions of Article 123(2) EPC. The question was therefore, to know whether a device combining the possibility of delivery with a “catheter” and with a “straightening mandrel” was disclosed in the “application as filed”.

In the description as filed, delivery with a “catheter” and delivery with a “straightening mandrel” were presented as alternatives. Furthermore, figures 2 to 5 illustrated a device using a “catheter” for delivery whereas figure 6 illustrated a device using a “straightening mandrel” and the presentation of the drawings in the description specified that “Figure 6 shows another embodiment of present invention for use with a straightening mandrel” (emphasis added).

The Opposition Division considered that claims 25 and 26 were not contrary to Article 123(2) EPC as the skilled person would consider that a device appropriate for delivery via a catheter is also appropriate for delivery by a straightening mandrel.
This decision has however been reversed by the Board of Appeal who considered that claims 25 and 26 were contrary to Article 123(2) EPC because no support for claims 25 and 26 as granted could be found in the claims as originally filed and none of the embodiment described in the application discloses an elongated member which is intended for use with both delivery devices.

Even though the Board of Appeal recognized that the skilled person might assume that a tissue connecting device suitable for delivery with a mandrel might in practice also be suitable to be delivered with a catheter, it considered there were - in the “application as filed” - no direct and unambiguous disclosure of a tissue connecting device suitable to be used with either delivery device.

As a consequence, in order to avoid an addition of feature to be considered as contravening the provisions of Article 123(2) EPC, the application should preferably be drafted having in mind all possible combinations of features. In particular, it is advisable to use multiple dependencies of the claims wherever it is possible, and also explicitly mention in the description that certain features can be used not only as alternatives but also in combination.

- **Intermediate generalisation**

Before the EPO, an intermediate generalisation is considered to be an undisclosed combination of selected features, lying somewhere between an originally broad disclosure and a more limited specific disclosure.

In principle, such intermediate generalisation is contrary to Article 123(2) EPC as it was not disclosed in the “application as filed”. However, there is an exception where such selection of features would be acceptable as defined by the Boards of Appeal and enshrined in the Guidelines for Examination at the EPO, where part H-V-3.2.1 states that (emphasis added):

> Extracting a specific feature in isolation from an originally disclosed combination of features and using it to delimit claimed subject-matter may be allowed only if there is no structural and functional relationship between the features.

This part of the Guidelines for Examination also reminds us of the test that has been developed by the Boards of Appeal to assess whether an amendment that would *prima facie* be considered as an intermediate generalisation could fulfil the requirements of Article 123(2) EPC:
When a feature is taken from a particular embodiment and added to the claim, it has to be established that:

- the feature is not related or inextricably linked to the other features of that embodiment and
- the overall disclosure justifies the generalising isolation of the feature and its introduction into the claim.

All the other principles that have been mentioned in part I. above should also be followed. In particular, it has to be ensured that “the skilled person is not presented with information which is not directly and unambiguously derivable from the originally filed application”.

For illustrative purposes, we refer to the decision T2350/10 of the Board of Appeal in the opposition against European patent EP 1 597 584 B1. Below is a comparison between claim 1 as filed and claim 1 of the first auxiliary request in the Appeal procedure (emphasis added).

**Claim 1 as filed**

1. A method for determining the quantity of a pre-synaptic neuromuscular blocking substance in a sample which comprises the following steps:
   (i) determining the minimum voltage $V_m$ needed to induce the contraction of muscle tissue, said muscle tissue [...];
   (ii) adding [...];
   (iii) electrically stimulating, [...];
   (iv) comparing [...] and thereby determining [...].

**Extract of description - Page 10 lines 2-18 (Ex 1) & page 13 lines 1-10 (Ex 3):**

Experimental protocols describing the selection of an intercostal nerve which can be stimulated at a voltage < 10V

**Claim 1 - Auxiliary request 1 (Appeal)**

1. An *ex vivo* method for determining the quantity of a pre-synaptic neuromuscular blocking substance in a sample which comprises the following steps:
   (i) selecting a motor nerve of muscle tissue capable of being electrically stimulated below 10V to induce the contraction of the muscle tissue, and determining the minimum voltage $V_m$ needed to induce the contraction of the muscle tissue, said muscle tissue [...];
   (ii) adding [...];
   (iii) electrically stimulating, [...] by train pulse electrical stimulations [...];
   (iv) comparing [...] and thereby determining [...].

The “application as filed” does not disclose the step of selecting a muscle tissue capable of being electrically stimulated at 10V.
Examples 1 and 3 that describe a stimulation at a voltage <10V are given in a very specific common context, i.e. for a particular animal model (Wislar rats), a specific muscle tissue (rib cage muscle tissue), specific nerves (intercostal nerves), and with specific stimulation conditions.

It cannot be concluded from these examples or from the general disclosure that the exact same minimum voltage of 10V would be required for other animal models, different muscle tissue and nerves, and in other stimulation conditions.

The Board of Appeal thus considered that the amendment made to the claim was an unallowable intermediate generalisation.

With this concept of unallowable intermediate generalisation, using Examples or Drawings as a basis of amendments can be problematic, except if the amendment relates to a feature obviously independent from the other features, and is preferably described in different contexts. The burden of proof however lies on the applicant/patentee who has to demonstrate that the extraction of the feature is acceptable.

As practical advice, an application to be prosecuted in Europe should preferably be drafted with an explicit description of preferred combinations of specific features, rather than by providing exhaustive lists of features without any description of their interactions or possible combinations.

It must be remembered that the application as filed cannot be considered as a reservoir of features where the applicant can cherry-pick in order to build a specific embodiment having absolutely no basis in the application as filed.

In general, combinations of features that have not been described will be considered as new technical information and thus not acceptable as amendment.

- **Disclaimers**

The subject matter of a claim is normally defined in terms of positive features indicating that certain technical elements are present. Exceptionally, however, the subject-matter may be restricted using a negative limitation - also referred as disclaimer - expressly stating that particular features are absent.

The issue with regard to the acceptability of a disclaimer as an amendment to the application will not be reviewed in detail in the present paper. One has however to bear in mind that the
issue of allowability of disclaimer is handled differently, depending on whether the disclaimer was disclosed in the application as originally filed or not.

Amending the claims by adding a disclaimer that is disclosed in the application as originally filed raises no issue, as it is clearly part of the subject-matter disclosed in the “application as filed”. Such disclaimer is thus acceptable.

The allowability of undisclosed disclaimer is much more questionable and has led to several referrals to the Enlarged Board of Appeal, which has given some responses as to the way to handle such disclaimers, first in decisions G1/03 & G2/03, and more recently in decision G2/10.

In decision G2/10, the Enlarged Board of Appeal focused on the allowability of disclaimers relating to subject-matter disclosed as part of the invention in the application as filed. The Enlarged Board of Appeal considered that such disclaimer could possibly be accepted provided that the claimed subject-matter with the disclaimer (i.e. after the amendment) does not bring new technical information to the skilled person in comparison with the technical information derivable from the application as filed.

The allowability of disclaimers relating to subject-matter absolutely not disclosed (even as part of the invention) in the application as filed is much more restrictive. Such types of disclaimer will be acceptable only if it falls within one of the few exceptions stated in decisions G1/03 & G2/03 of the Enlarged Board of Appeal:

- to restore novelty over a conflicting application (prior art document under Article 54(3) EPC);
- to restore novelty over an accidental anticipation (document so unrelated to and remote from the claimed invention that the skilled person would never have taken it into consideration when making the invention); or
- to remove subject-matter which is excluded from patentability for non-technical reasons (such as human embryonic cells, for instance).

In addition, a disclaimer relating to subject-matter not disclosed in the “application as filed” should remove no more than is necessary (a very precise and accurate assessment of the disclosure of the conflicting application or accidental anticipation is thus necessary) and must meet the clarity and conciseness requirements of Article 84 EPC.
Further, a disclaimer relating to subject-matter not disclosed in the “application as filed” is not allowable if the limitation is or becomes relevant for assessing sufficiency of disclosure or for assessing novelty or inventive step of the claimed subject matter over non-accidental prior art under Article 54(2) EPC. Because of that, the allowability may vary over time, in particular if new prior art documents are identified or if assessment of the disclosure of the conflicting application or accidental anticipation was not accurate.

During examination, the newly unallowable disclaimer may - if necessary - be removed from the claim. This is, however, not the case in opposition proceedings, since removal of the disclaimer would extend the protection conferred by the patent, which is contrary to Article 123(3) EPC. In opposition proceedings, an unallowable disclaimer may lead to the so-called “unescapable trap” of Article 123(2) EPC and 123(3) EPC.

It should thus be advised, each time a disclaimer of subject-matter not disclosed in the “application as filed” is useful, to consider the possible later unallowability of the disclaimer and also to insert in the claims a narrower dependent claim, comprising positive features implicitly excluding the subject matter to be excluded, but without a disclaimer.

- **Additional limits for amending the claims in Europe**

Even though Article 123(2) EPC is the main safeguard that regulates amendments in a European patent application or European patent, there are other provisions in the European Patent Convention that further limit the possibilities for the applicant/patentee to amend the application, in particular the claims.

- **During prosecution of the European patent application**

The application under prosecution, including the amended parts, must satisfy all the requirements of the European Patent Convention.

Consequently, when amending the claims during the prosecution of the European patent application, care should be taken not to introduce new deficiencies in the claims.

In particular, the object of the amended claims should be clear pursuant to the requirements of Article 84 EPC.

In addition to those provisions defining the frame of allowability of amendments, there are also provisions in respect of the admissibility of the amendments.
Rule 137 EPC defines the time-frame for introducing amendments during the prosecution of European applications and also restricts the extent to which the claims can be amended. Pursuant to the provisions of paragraph 5 of Rule 137 EPC, it is namely not possible to amend the claims so that they relate to subject-matter having been specifically excluded from the search, or subject-matter which has not been searched and which does not combine with the originally claimed invention or group of inventions to form a single general inventive concept.

This specific provision of Rule 137 EPC is now often used by the European examiners to prevent the application from shifting the main focus of the claims. The appropriate drafting of dependent claims could however help with avoiding being restricted by this rule.

- **After grant of a European patent**

After grant, the European patent can still be amended either in proceedings before the EPO - such as the Opposition proceedings of Article 99 EPC or the Limitation proceedings of Article 105a EPC - or in proceedings before National Courts.

The main restriction in respect to the amendment of claims in post-grant proceedings - coming in addition to the limitations of Article 123(2) EPC - is established by Article 123(3) EPC that forbids any amendment that would extend the protection conferred by the European patent.

In a similar way as for any amendment made during the prosecution of the European patent application, any amendment made to the European patent must also satisfy all the requirements of the European Patent Convention, in particular the clarity of the claims pursuant to Article 84 EPC.

Where lack of clarity is not a valid ground to put forward in opposition against a granted claim, the assessment of clarity of the claim becomes relevant when the claims are amended. Such ground is often used by opponents to prevent the patentee from amending the claims and is always a central point of discussion.

Regarding such requirements of clarity for any claim amended in Opposition proceedings, a referral is pending before the Enlarged Board of Appeal, under reference G3/14, to decide whether this criterion should be applied to amendments of the claims based on granted claims. In particular, the question is asked whether the clarity of an amended claim based on the combination of an independent granted claim with some elements of a granted dependent claim should be examined or not.
Conclusion

Even though there are a lot of restrictions in respect to amendments under the European practice, the Case Law of the Enlarged Board of Appeal and the Boards of Appeal sanctioned defining tests in order to assess as objectively as possible whether an amendment is allowable or not.

These tests and rules, focused on the amendments of European patent applications, should be used and taken into consideration when drafting the application so that the content of the “application as filed” can effectively and efficiently be used to elaborate allowable amendments to the application, in particular amendments to the claims.

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Fifteen partners head a team of more than 200 people whose skills are put into practice in every strategic aspect of Intellectual Property - business intelligence and information search, license agreements, IP portfolio audits, partnership negotiations, acquisition of industrial property rights, litigation.
Already well implanted in France with headquarters located in Paris along with several local branches (Lyon, Rennes, Grenoble, Montpellier, Toulouse and Caen), REGIMBEAU strengthened its presence in Europe with the opening in September 2012, of a Munich branch situated close to the European Patent Office (EPO). REGIMBEAU has also put a specialized organization into place, with a core team dedicated to handling EPO proceedings for foreign applicants.