



# Added subject matter and amendment of claim (article 123(2) EPC)

• <u>Remainder of the claim after introduction of a</u> <u>disclaimer has to be, be it explicitly or implicitly,</u> <u>directly and unambiguously disclosed to the skilled</u> <u>person using common general knowledge, in the</u> <u>application as filed</u>

• 1a. An amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123(2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.

• 1b. Determining 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.

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## Enlarged Board of Appeal EPO, 30 August 2011

(W. van der Eijk, P. Carlson, I. Beckedorf, C. Vallet, F. Blumer, H. Meinders, W. Sieber)

#### Case number: G 0002/10

Decision of the Enlarged Board of Appeal

of 30 August 2011

Appellant: The Scripps Research Institute, 10550 North Torrey Pines Road, La Jolla, CA 92037 (US)

Representative: Almond-Martin, Carol Ernest Gutmann - Yves Plasseraud S.A.S. 88, Boulevard des Belges, F-69452 Lyon Cedex 06 (FR)

Referring Decision: Interlocutory decision of the Technical Board of Appeal 3.3.08 dated 25 June 2010 in

case T 1068/07.

Composition of the Board:

Chairman: W P. Messerli

Members: B. Günzel, A. S. Clelland, U. Oswald, B. Schachenmann, J.-P. Seitz, A. Wirén

Summary of Facts and Submissions

I. The referred question

By interlocutory decision T 1068/07 of 25 June 2010, Technical Board of Appeal 3.3.08 referred the following question to the Enlarged Board of Appeal:

Does a disclaimer infringe Article 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed?

II. The appealed decision of the examining division

The appeal proceedings before the referring Board concern the appellant's appeal against the decision of the examining division of 2 February 2007 refusing European patent application No. 98 920 015.9. The examining division decided that both the appellant's main and (first) auxiliary request did not fulfil the requirements of Article 123(2) EPC. The application as filed provided no basis for the disclaimers introduced in the respective claims 1.

III. The claims underlying the referring decision

The application relates to catalytic (enzymatic) DNA molecules capable of cleaving other nucleic acid sequences or molecules, particularly RNA, in a site-specific manner.

Claim 1 of the main request reads as follows:

"1. A catalytic DNA molecule having site-specific endonuclease activity specific for a nucleotide sequence defining a cleavage site in a preselected substrate nucleic acid sequence,

said catalytic molecule having first and second substrate binding regions flanking a core region,

said molecule having the formula:

5' (X-R) - GGCTAGCT\*\*(8)ACAACGA - (X) 3' wherein

each X is any nucleotide sequence,

(X-R) represents said first substrate binding region,

(X) represents said second substrate binding region,

R is a nucleotide capable of forming a base pair with a pyrimidine in the preselected substrate nucleic acid sequence,

 $T^{**}(8)$  may be replaced by C or A,

said first substrate binding region having a sequence capable of binding through complementary base-pairing to a first portion of said preselected substrate nucleic acid sequence,

said second substrate binding region having a sequence capable of binding through complementary base-pairing to a second portion of said preselected substrate nucleic acid sequence,

wherein the first substrate binding region does not have the sequence 5' CTTTGGTTA 3' or 5' CTAGTTA 3',

wherein the second substrate binding region does not have the sequence 5' TTTTTCC 3'  $\,$ 

and wherein the said catalytic DNA molecule does not show site-specific endonuclease activity for the sequence:

# 5' - GGAAAAAGUAACUAGAGAUGGAAG - 3' (SEQ ID NO 135)."

(emphasis added by the Enlarged Board)

As regards claim 1 the appellant's auxiliary request I reads as the main request, except for the incorporation into claim 1 of the indication that "R" represents A or G from claim 2.

As regards their respective claims 1, the appellant's auxiliary requests II and III, filed before the referring Board in response to a communication by the Board, read as the main request, except that the final portion of claim 1 of the main request reading "wherein the first substrate binding region does not have the sequence [...] (SEQ ID No. 135)" is replaced by a wording which in auxiliary request II reads:

"... with the proviso that said catalytic molecule is not a molecule in which the first and second binding regions can bind through complementary base-pairing to a substrate nucleic acid which is:

5' - GGAAAAAGUAACUAGAGAUGGAAG - 3' (SEQ ID NO 135).";

and in auxiliary request III reads:

"... with the proviso that said catalytic molecule is not a molecule which shows site-specific intermolecular catalytic cleavage of the substrate:

5' - GGAAAAAGUAACUAGAGAUGGAAG - 3' (SEQ ID NO 135)

under conditions of 2 mM MgCl2, 150 mM KCl, pH 7.5, 37°C, for a rate of about kcat = 0.01 min\*\*(-1)."

IV. The decision of the examining division

The examining division had rejected the main and first auxiliary requests filed before it by the applicant (appellant) on the grounds that the disclaimer contained therein was not disclosed as such in the application as filed and that furthermore, the requirements of decisions G 1/03 and G 2/03 (OJ EPO 2004, 413 and 448, hereinafter: decision G 1/03, unless a different specific reference is made) were not met. The disclaimers served to render the subject-matter of claim 1 novel under Article 54(2) EPC over D1, but D1 clearly belonged to the same technical field as it also dealt with catalytic DNA molecules. It was thus not so unrelated to and removed from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention. Moreover, D1 had the same inventor and applicant as the application in suit and its content was to a large extent identical to that of the application.

V. The referring decision

The referring Board considers claim 1 in both the appellant's main request and its auxiliary request I to offend against Article 123(2) EPC. According to the referring Board these claims are limited by "three negative features" which are not disclosed in the application as filed. The exclusion from the ambit of protection of claim 1 of the specific (first and second) substrate binding arms and of the specific substrate sequence of the prototype "10 to 23" motif (cf. Figures 8 and 9) by the negative features is said to constitute a selection within the broader outline of the changes proposed in example 6, in particular on page 87, lines 24

to 28. For this selection no direct and unambiguous support is found in the application as filed (see point 11. of the Reasons).

By contrast, in auxiliary requests II and III the negative features characterising claim 1 of the preceding requests have been replaced by disclaimers, the subject-matter of which was disclosed as an embodiment of the invention. As was observed in point 4.2.3 of decision G 1/07, following decision G 1/03, which dealt with the issue of so-called undisclosed disclaimers, different opinions have been expressed in the jurisprudence of the boards of appeal as to whether the findings of the said decisions of the Enlarged Board relate also to disclaimers disclaiming embodiments which are disclosed in the application as filed as being part of the invention or whether they do not relate thereto. In the case before the referring Board, whether the first approach is followed rather than the second, makes a decisive difference. In the first case auxiliary requests II and III would have to be rejected under Article 123(2) EPC, with the consequent dismissal of the appeal. In the second case these requests would be considered not to offend against Article 123(2) EPC and the decision under appeal could be set aside.

VI. The course of the proceedings before the Enlarged Board

By decision of 6 August 2010 the Enlarged Board invited the President of the EPO to comment in writing on the point of law referred to the Enlarged Board and also issued an invitation for third parties to file comments. The President of the EPO and a number of third parties submitted comments in writing. On 18 March 2011 the Enlarged Board issued a summons to attend oral proceedings and thereafter, on 21 June 2011, a communication drawing attention to a number of issues that appeared of significance for discussion in the oral proceedings. Oral proceedings were held on 4 August 2011. At the end of the oral proceedings the chairman announced that the Enlarged Board would give its decision in writing.

VII. The appellant's submissions

The submissions of the appellant may be summarised as follows:

Decision G 1/03 does not apply to disclaimers excluding disclosed embodiments. The legal analysis by the Enlarged Board in decision G 1/03 was determined by the questions put to it. These questions did not include an assessment of the situation where the subject-matter to be excluded was disclosed only in positive terms. Furthermore, the manner in which the Enlarged Board defined how the disclaimer should be drafted (in point 3. of the Reasons), i.e. that it should not remove more than is necessary to restore novelty or to disclaim subjectmatter excluded from patentability for non-technical reasons, shows that  $\underline{G 1/03}$  was not intended to apply to disclaimers for positively disclosed embodiments, since in the latter case the wording of the disclaimer is imposed by the wording of the embodiment. This difference between the two types of disclaimers clearly illustrates their fundamentally different nature.

As regards point 2.5 of the Reasons of decision <u>G 1/03</u>, relied on by the Board in decision T 1050/99, the cited passage of the Enlarged Board's decision does not justify the Technical Board's conclusions. There is nothing in that section of <u>G 1/03</u> to suggest that the Enlarged Board was considering a situation "where the disclaimer is not disclosed in the application as filed and the subject-matter excluded by it is". On the contrary, both decisions T 170/87 and T 313/86, which are the only decisions referred to in this passage of <u>G 1/03</u> in the context of exclusion of subject-matter, addressed the question of disclaimers in the absence of support for the subject-matter to be excluded.

In its decision G 1/07 the Enlarged Board addressed the issue of different opinions having been expressed in the jurisprudence of the boards of appeal on the issue and defined only two possibilities with regard to the approach to be applied when assessing disclaimers for disclosed embodiments, namely:

# (a) application of $G \frac{1}{03}$ or

(b) application of the jurisprudence following decision T 4/80, as summarized in decision T 1107/06. Since only two alternatives were indicated by the Enlarged Board in decision G 1/07, the approach to be adopted must be the approach as defined in T 4/80 and the subsequent decisions, including T 1107/06. This approach is also that still summarised in the previous version of the Guidelines for Examination as published in June 2005 (see III, 4.2).

A disclaimer whose subject-matter is disclosed as an embodiment of the invention in the application as filed is not contrary to Article 123(2) EPC. In such a case the applicant clearly does not draw any unwarranted advantage within the meaning of decision G 1/93 (point 9. of the Reasons), since he or she is merely claiming the originally disclosed invention less a particular embodiment, both of which were described initially. Therefore the legal security of third parties cannot be jeopardised by such a disclaimer.

In accordance with decision T 1107/06 the question to be asked is not whether it can be inferred from the application as filed that the applicant intended to exclude the subject-matter of the disclaimer, but rather whether the subject-matter remaining in the claim after insertion of the disclaimer finds support (point 45. of the Reasons). In that decision the Technical Board concluded that the skilled person faced with the generic disclosure of the invention and the specific disclosure of an illustrative embodiment falling within the generic disclosure will normally infer that all the other embodiments comprised in the generic disclosure without being mentioned specifically also form part of the invention. The non-exemplified or non-preferred embodiments are thus implicitly disclosed as the logical complement of the explicitly mentioned embodiments. This "logical complement" approach is the correct approach. Indeed, as a matter of logic, the singling out of a small group (Y) within a larger group (X), necessarily gives two groups i.e. the small group (Y) and the remaining group which is the larger group minus the smaller group (X-Y). A disclosure which singles out the subgroup (Y) from the larger group (X) thus implicitly describes the remaining group (X-Y). A claim directed to (X-Y) is therefore fully supported by the disclosure of (Y) singled out from (X).

The boards of appeal regularly accept that a given subject-matter can be defined in positive or negative terms, one being the complement of the other. Reference is made to decisions T 4/80 and T 448/93.

VIII. The appellant's requests

In the oral proceedings before the Enlarged Board the appellant requested that the answer to the referred question be no, provided there is a clear and unambiguous disclosure of the subject-matter remaining in the claim.

IX. The comments made by the President of the EPO

On the basis of established case law following decision T 4/80 the first instance practice was to accept that, if specific subject-matter was originally disclosed as a possible embodiment of the invention, a disclaimer could be introduced into the claim in order to exclude this embodiment from the scope of protection, provided the subject-matter remaining claimed could not be defined more clearly and concisely by positive features or if such positive definition would unduly limit the scope of the claim. This practice did not change after decision  $G_{1/03}$ . Based on the phrasing of the question referred in case G 1/03, but in particular also on the text of the answers given by the Enlarged Board of Appeal, it was considered that the Enlarged Board of Appeal dealt only with the situation in which neither the disclaimer nor the subject-matter excluded by the disclaimer was disclosed in the application as filed. However, after a number of decisions concluded that disclaimers based on embodiments which are disclosed in the original application as part of the invention have to be considered as undisclosed disclaimers to which the criteria set out in G 1/03 apply, the practice of the first instance department was adapted to the new jurisprudence. This practice was not changed again in the light of T 1107/06. The current practice can be seen from the Guidelines published in April 2010.

As was said in decision T 1107/06, point 45. of the Reasons, the decisive question to ask under Article 123(2) EPC is not whether the skilled person could infer from the original disclosure that the applicant intended to exclude the disclaimed subject-matter from the scope of protection. Rather it has to be ascertained whether there is a clear and unambiguous disclosure, be it explicit or implicit, of the subject-matter remaining in the claim. When there is a generic disclosure of the invention together with a specific disclosure of an illustrative or preferred embodiment falling under the generic disclosure, the skilled person will normally infer that all the other embodiments comprised in the generic disclosure without being mentioned specifically also form part of the invention. The non-exemplified or nonpreferred embodiments are thus implicitly disclosed as the logical complement of the exemplified or preferred embodiments.

It follows that a disclaimer excluding protection for subject-matter disclosed as an embodiment of the invention in the application as filed does not necessarily infringe Article 123(2) EPC. Where the subject-matter remaining in the claim is not directly and unambiguously derivable from the application as filed, the criteria established in <u>G 1/03</u> regarding the allowability of a disclaimer should be applied.

The amendment's admissibility is a matter which must be assessed in each particular case on its own merits.

Such a view would and should be consistent with the determination of the disclosure and the rights derivable therefrom in other provisions which build on the disclosure of a document.

Regarding novelty this would imply that an application with a generic disclosure of the invention together with a specific disclosure of an illustrative or preferred embodiment falling under the generic disclosure may be novelty destroying for a later application containing the disclaimer.

Taking the disclosure as the basis for the right to priority, as stated in decision <u>G 2/98</u> and confirmed in <u>G 1/03</u>, this means that a disclaimer not infringing Article 123(2) EPC, which is allowable during the prosecution of a European patent application, does not change the identity of the invention within the meaning of Article 87(1) EPC. By the same token, its introduction should also be allowable when drafting and filing a divisional application if the earlier application as filed does not contain the disclaimer but discloses its subject-matter as an embodiment of the invention.

Disclaiming disclosed subject-matter may also become relevant in order to avoid double patenting in the case of overlapping claims between two EP applications, for instance parent and divisional applications or priority and successive applications or between the patent granted on a European patent application and the patent granted on a preceding application in a designated state, the priority of which is claimed in the European application, if double patenting is prohibited in the designated state. A disclaimer should also be allowable where a third party files a new application under Article 61(1)(b) EPC confined to that part of the original subject-matter to which it has become entitled. An additional reason for a disclaimer could be that the subject-matter is excluded from patentability for nontechnical reasons.

In any case, clear guidance should be given regarding the requirements concerning the allowability of disclaimers, including suitable transitional arrangements, if appropriate, for pending applications and patents.

X. The submissions of the amici curiae

Amici curiae briefs were received from Astra Zeneca AB, the Chartered Institute of Patent Attorneys (CIPA) and several professional representatives. The submissions made were essentially:

- The referred question is unclear and the answer depends on the individual circumstances of the case under consideration. Disclaiming a disclosed embodiment does not jeopardise legal certainty for third parties and does not improve the applicant's position. - The applicant may have a legitimate interest in further pursuing a claimed generic invention and a specific embodiment thereof in related applications, either to obtain rapid grant for the specific embodiment or for funding or licensing purposes.

- G 1/03 did not decide the presently referred issue.

- The test to be applied on the assessment of the disclaimer is whether the specific disclaimer made results in new subject-matter being disclosed.

- As a matter of logic the disclosure of a narrow region B (whether having an advantageous feature or not) within a general region A inevitably and inescapably discloses the region A-B. In terms of technical teaching disclaiming B has no technical teaching on its own. It merely limits the scope of the claim.

- A priori, under Article 123(2) EPC a disclaimer can be introduced for any purpose, i.e. the disclaimed embodiment may in fact be patentable.

- The prior art situation is not relevant for assessing the disclaimer under Article 123(2) EPC. Otherwise the disclaimer could initially be held to satisfy Article 123(2) EPC and later be held to violate Article 123(2) EPC because new prior art is found.

- The applicant should not be in a worse position through disclosing a disclaimed embodiment than by not disclosing a disclaimed embodiment. If the relevant prior art cannot be considered as an accidental anticipation of the disclaimed embodiment, then the applicant may have to show that the embodiments remaining within the scope of the claim are patentable in comparison with the disclaimed embodiment. To that extent exactly the same situation can arise as in cases where the claim is limited by some other form of amendment.

## **Reasons for the decision**

#### 1. Admissibility of the referral

In decision G 1/07 (OJ EPO 2011, 134, point 4.2.3 of the Reasons) the Enlarged Board of Appeal pointed out that it was aware that, subsequent to decisions <u>G 1/03</u> and G 2/03 (OJ EPO 2004, 413 and 448) different opinions have been expressed in the jurisprudence of the boards of appeal on whether decisions <u>G 1/03</u> and G 2/03 relate to the disclaiming of embodiments which are disclosed as part of the invention in the application as filed or whether in that situation the jurisprudence as previously established following decision T 4/80 (OJ EPO 1982, 149) continues to apply. Reference was made by the Enlarged Board to decision T 1107/06 of 3 December 2008, points 31. et seq. of the Reasons, and the decisions cited therein.

In spite of the somewhat broad wording of the referred question, which asks generally whether disclaiming an embodiment disclosed in the application as filed as an embodiment of the invention infringes Article 123(2) EPC, it is to be understood from points 15. and 16. of the Reasons of the referring decision that the referral was made mainly, if not exclusively, in order that the divergence of views identified in decisions T 1107/06 and G 1/07 could be clarified.

There is, furthermore, a divergence of views in the jurisprudence of the boards of appeal not only with

regard to the question of what the Enlarged Board actually decided in decision G 1/03 but also with respect to the question of what the right solution to the question ought to be. Is it the application of the criteria set out in decision <u>G 1/03</u> or should the relevant test be whether the subject-matter remaining in the claim after the introduction of the disclaimer was disclosed in the application as filed, as was held in decision T 1107/06? This question is indisputably also a point of law of fundamental importance within the meaning of Article 112(1) EPC and, since the question of compliance with Article 123(2) EPC is normally examined before substantive examination, the referral is admissible (see **G 1/03**, point 1.2 of the Reasons).

# **2.** The construction of the referred question

2.1 Disclaimer infringing Article 123(2) EPC?

The referring Board has asked whether a disclaimer infringes Article 123(2) EPC if its subject-matter was disclosed as an embodiment of the invention in the application as filed. However, since Article 123(2) EPC deals with amendments and since the disclaimer as such defines subject-matter that is not claimed, the question is construed as intended to ask whether an amendment to a claim by the introduction of a disclaimer infringes Article 123(2) EPC if the subject-matter of the disclaimer was disclosed as an embodiment of the invention in the application as filed.

# 2.2 The term "disclaimer"

In decision <u>G 1/03</u> (point 2. of the Reasons) the Enlarged Board of Appeal gave a definition of the term "disclaimer", which states that in accordance with consistent practice, the term "disclaimer" is used in the decision as meaning an amendment to a claim resulting in the incorporation therein of a "negative" technical feature, typically excluding from a general feature specific embodiments or areas. This is the understanding of the term "disclaimer" on which the present decision is also based.

## 2.3 The term "embodiment"

The referring Board has drafted the question of the infringement of Article 123(2) EPC on the basis that the disclaimed subject-matter is an "embodiment" of the invention. The term "embodiment" is commonly used to define a specific combination of features or a specific mode of carrying out the invention, by contrast to a more abstract definition of features which can be carried out in more than one way.

As regards disclaimers, it is, however, not generally so that only one specific embodiment is excluded from protection. On the contrary, disclaimers are often defined in much broader terms. The disclaimers then - at least potentially - exclude a plurality of embodiments, a whole (sub-) group thereof or a whole, even if limited, area falling within the ambit of a generic claim. In this respect, the Enlarged Board notes that e.g. in claim 1 of auxiliary request III all catalytic molecules are excluded from protection which show site-specific intermolecular catalytic cleavage of the substrate corresponding to a defined portion of sequence ID number 135 under defined conditions.

The main problem of the compatibility of disclosed disclaimers with Article 123(2) EPC does not lie in one specific "embodiment" of an invention being disclaimed from a broad generic claim. Rather, it arises in those cases in which a whole area or subclass is disclaimed. It is cases of this kind that have given rise to doubts whether, after the introduction of such a broad disclaimer, the subject-matter remaining in the claim is still the same as that formerly claimed, and have prompted the idea that, when the requirements of Article 123(2) EPC are examined, the nature of the subjectmatter remaining in the claim must be assessed. It appears immediately evident that the nature of the question differs according to whether only one specific embodiment is disclaimed from a generally drafted claim, or whether, on the other hand, a whole subgroup or area is disclaimed.

In decision <u>G 1/03</u>, point 2.1.3 of the Reasons, the Enlarged Board defines the possible contents of a disclaimer in a much broader sense than by referring to the exclusion of an embodiment. In the context of explaining why, for the purpose of delimiting the claimed-subject matter with respect to a conflicting application, a disclaimer is not in contradiction to Article 123(2) EPC, the Enlarged Board speaks very generally of "an invention comprising "different specific embodiments or groups thereof" having been disclosed in the application as filed, a "part of which" is excluded from the requested protection. There is no definition of a degree of narrowness required from the part to be excluded in order to be the potential subject-matter of a disclaimer.

This explains the broad wording of answer 1 in decision <u>G 1/03</u>, which does not use a narrow term such as "embodiment". Instead, it answers the referred question generally, with respect to "subject-matter" excluded by the disclaimer, in correspondence to the terminology used in question 1 of referring decision T 507/99 (OJ EPO 2003, 225).

For these reasons, the use of the term "embodiment" in the referred question can not be a reason for construing the question too narrowly. All - and in particular the critical - uses of disclaimers, i.e. disclaimers excluding whole (sub)groups of embodiments or areas from the claimed subject-matter need to be considered in order to deal with the referred question in an appropriate way. As a consequence, the Enlarged Board holds that the term "embodiment" in the referred question should be understood as addressing the issue of disclaiming "subject-matter". This term will figure in the Enlarged Board's answer.

# 3. Did <u>G 1/03</u> decide the issue of disclaimers disclaiming subject-matter disclosed in the application as filed?

In the decisions of technical boards of appeal cited in decision T 1107/06, point 42. of the Reasons, the expression "disclaimer which is not disclosed in the application as filed" in answer 2 of decision G 1/03 has been read as meaning that the criteria set out in answer 2 were meant to apply to all cases in which the disclaimer as such was not disclosed in the application

as filed and hence also to cases in which, albeit the disclaimer not being disclosed as such, its subject-matter was disclosed in the application as filed.

Such a reading of decision  $\underline{G \ 1/03}$  is incorrect, for the following reasons:

3.1 It is particularly clear from question 1 of the first referring decision, T 507/99 (Headnote), that that referral was only directed to the situation in which neither the disclaimer nor the subject-matter excluded by it from the scope of the claim has a basis in the application as filed. Question 1 sets out this condition explicitly, the referring Board having ascertained in point 3. of the Reasons that in the case under consideration neither the disclaimers as such nor the excluded subject-matter had been disclosed in the application as filed.

The second referring decision, T 451/99 (OJ EPO 2003, 334, Headnote), uses the term "disclaimer not supported by the application as filed" in the first referred question, but it is clear, in particular from points 4. and 24. of the Reasons, that by using this term the referring Board was - also - addressing a situation in which neither the disclaimer as such nor the excluded subject-matter was disclosed in the application as filed.

3.2 In spite of some differences in wording, in both referring decisions the further questions asking the Enlarged Board to define the criteria to be applied in assessing the admissibility of a disclaimer, refer back to the respective first question put. In both decisions, the further questions were put to the Enlarged Board only for the event that the Enlarged Board did not answer question 1 by saying that an amendment to a claim by the introduction of a disclaimer is unallowable under Article 123(2) EPC for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim has a basis in the application as filed (i.e. is supported by the application as filed, in the terminology of T 451/99).

3.3 The Enlarged Board's answers follow exactly the structure of the referred questions. They start by giving the basic principle in answer 1. It is expressly stated therein that the answer relates to the case in which neither the disclaimer nor the subject-matter excluded by it from the scope of the claim has a basis in the application as filed. Answer 2 and its sub-answers then address the further referred questions and define in more detail the criteria to be applied for assessing the allowability of such a disclaimer.

In this respect also following the structure of the referred questions, answer 1 is, however, only drafted in negative terms by giving the reason for which an amendment may not be refused under Article 123(2) EPC (i.e. not for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim has a basis in the application as filed). It is, hence, clear that answer 1 only partly dealt with the referred questions and that further answers were required to settle them.

In such a situation, where an answer completes another answer in order to settle the questions posed, the questions all being defined by a particular set of circumstances (here the fact that neither the disclaimer

nor the subject-matter excluded by it has a basis in the application as filed), such further answer cannot be taken out of context or read in isolation. Just as for the further referred questions (see in this respect in particular decision T 507/99), answer 2 refers back to and further elucidates the criteria to be applied in the context of the basic answer given in answer 1. When read in the context of answer 1, it appears that the term "disclaimer which is not disclosed in the application as filed" used in answer 2 is the term linking this answer to answer 1. It may be that this passage of answer 2 could have been worded by repeating verbatim the corresponding formulation in answer 1. However, it can nevertheless be deduced clearly from the above-described structure of the answers - which corresponds to the structure of the referred questions - that the Enlarged Board's answer to subsidiary question 2 refers to the situation addressed in answer 1, i.e. to the situation in which neither the disclaimer nor the subject-matter excluded by it have a basis in the application as filed. In the Reasons of decision  $\underline{G 1/03}$  that situation is later referred to by the use of the term "undisclosed disclaimer" (see e.g. point 2.1 of the Reasons), and in the present case the same terminology will be used.

Hence, the controversial passage in answer 2 cannot be read to mean that the Enlarged Board intended to decide that a case not addressed by the referred questions, i.e. the situation in which the subject-matter excluded by the disclaimer is disclosed in the application as filed, was a case to which the criteria set up in answer 2 were to be applied.

3.4 In the absence of indications to the contrary, it can be presumed that the Enlarged Board would have clearly stated so if it had intended to give answer 2 a meaning going beyond the scope of the questions posed. Nor is there anything in the further text of decision <u>G 1/03</u> which indicates that the Enlarged Board envisaged that the requirements for the allowability of disclaimers, as set out in answer 2, should apply to the disclaiming of subject-matter disclosed in the application as filed.

3.5 Point 2.5 of the Reasons of decision G 1/03 does not support the conclusion drawn from that passage by the technical board in decision T 1050/99 of 2 January 2005, points 6. and 7.(d) of the Reasons, that  $G \frac{1}{03}$  also relates to disclaimers for disclosed subject-matter. In point 2.5 of the Reasons of decision G 1/03 the Enlarged Board generally addresses the question as to whether, if a claim comprises non-working embodiments, such embodiments may be disclaimed. It is nowhere mentioned that, although the object of the said decision was disclaimers for subject-matter which was not disclosed in the application as filed, the discussion in point 2.5 of the Reasons relates to the situation in which the non-working embodiments are disclosed in the application as filed. The fact that the two decisions cited by the Enlarged Board in this context, i.e. T 170/87 (OJ EPO 1989, 441, point 8.4 of the Reasons) and T 313/86 of 12 January 1988, referred to in decision T 170/87, addressed the question of disclaimers in the absence of disclosure of the subject-matter to be excluded in the application as filed, also points away from the interpretation of that passage in the sense advocated in decision T 1050/99.

3.6 Furthermore, as the appellant's representative has pointed out, the requirement laid down by the Enlarged Board in point 3. of the Reasons of decision  $G_{1/03}$  for drafting a disclaimer, i.e. that "the disclaimer should not remove more than is necessary to restore novelty..." is not suitable for the disclaiming of disclosed subjectmatter, since in that case the wording of the disclaimer must be configured in accordance with the disclosure of the disclaimed subject-matter in the application as filed. 3.7 In point 2. of the Reasons of decision G 1/03, the Enlarged Board explains why it uses the term disclaimer instead of the "undisclosed" term "unsupported" disclaimer, which had been used in referring decision T 451/99 for the situation in which neither the disclaimer as such nor the disclaimed embodiments were disclosed in the application as filed. As is apparent from the Enlarged Board's explanations, the only reason for the change in terminology adopted by it was to avoid any confusion between the requirements of Article 123(2) EPC and those of Article 84 EPC, which uses the term "supported".

3.8 For the Enlarged Board it is furthermore an important element in arriving at this conclusion that national decisions have taken the same stance and read decision G 1/03 in the same way ("Napp Pharmaceutical Holdings Ltd v. Ratiopharm GmbH and Sandoz Ltd", Court of Appeal (England and Wales), [2009] EWCA Civ 252, point 82. et seq. of the Reasons, with reference to T 1139/00; "Mundipharma Pharmaceuticals B.V. v. Sandoz B.V.", District Court of The Hague of 7 April 2010, case no. 340373/09-2029, point 4.11 et seq. of the Reasons). This has been made particularly explicit in the above cited decision of the District Court of the Hague, in which the Court sets out in a very comprehensive and convincing reasoning, which is analogous to the Enlarged Board's reasoning in the present decision, why it comes to the conclusion that decision G 1/03 only relates to the situations in which "neither for the disclaimer nor for the subject-matter of the disclaimer (i.e. that which is excluded) a basis can be found in the original application" (loc.cit., translation into English on file).

3.9 To conclude, it cannot be said that answer 2 of decision G 1/03 relates to the disclaiming of subjectmatter disclosed as part of the invention in the application as filed.

4. Does an amendment to a claim by the introduction of a disclaimer disclaiming subject-matter disclosed in the application as filed infringe Article 123(2) EPC?

# 4.1 The scope of the referred question

In point 15. of the Reasons of the referring decision the referring Board defines the purpose of the referral as being to clarify the controversial issue of whether the conditions set out in decision  $G_{1/03}$  apply to the disclaiming of disclosed subject-matter or whether the relevant test should be whether the subject-matter remaining in the claim after the introduction of the disclaimer is disclosed in the application as filed (see

also point 1. above). It is clear, however, that when considering and deciding the referred question, which has been drafted in a broader manner, the Enlarged Board cannot in any way be confined to deciding only on these two opposed alternative interpretations adopted by the boards of appeal. On the contrary, even though the Enlarged Board will consider what has been said on the matter in prior decisions, it is the Enlarged Board's role to define of its own motion the criteria determining when disclaiming disclosed subject-matter must be considered to infringe Article 123(2) EPC.

4.2 The text of Article 123(2) EPC

Article 123(2) EPC reads:

"(2) 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."

4.3 The basic principle underlying Article 123(2) EPC, in the jurisprudence of the Enlarged Board

The importance and the applicability, without exception, of Article 123(2) EPC was underlined in the jurisprudence of the Enlarged Board of Appeal as early as in its opinion G 3/89 and decision G 11/91 (OJ EPO 1993, 117 and 125, relating to amendments by way of correction). From these rulings it follows 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 a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed, points 1., 1.3 and 3. of the Reasons.

These findings were in principle confirmed in decision <u>G 1/93</u> (OJ EPO 1994, 541, answer 1, first sentence) with respect to the ground of opposition under Article 100(c) EPC and, on a more general level, in decision <u>G</u> 2/98 (OJ EPO 2001, 413), dealing with the requirement of the "same invention" under Article 87(1) EPC. In that decision the Enlarged Board also relied on a disclosure test for determining whether the later application is for the same invention as the priority application and made explicit reference to the disclosure test applied under Article 123(2) EPC (answer, see also point 1. and 9. of the Reasons).

In decision <u>G 1/93</u>, concerned with the relationship between paragraphs 2 and 3 of Article 123 EPC in the situation of the patentee being caught in a so-called "inescapable trap", the Enlarged Board stated with respect to the argument advanced of there being a mutual relationship between paragraphs 2 and 3 of Article 123 EPC, the one to be applied as primary and the other as subsidiary depending on the facts of the individual case: "This interpretation is not in line with the mandatory character of Article 123(2) EPC, as explained by the Enlarged Board in its opinion in case <u>G 3/89</u> (OJ EPO 1993, 117)" (point 13. of the Reasons). In decision <u>G 1/93</u> the Enlarged Board however conceded that, where an undisclosed limiting feature without providing a technical contribution to the subjectmatter of the claimed invention - merely excludes protection for part of the subject-matter of the claimed invention as covered by the application as filed, the adding of such a feature cannot reasonably be considered to give any unwarranted advantage to the applicant and is, on a proper interpretation of Article 123(2) EPC, therefore not to be considered as subject-matter extending beyond the content of the application as filed within the meaning of that provision (point 16. of the Reasons).

It is, however, evident from the context of these findings that by introducing the "technical contribution" criterion the Enlarged Board did not intend to amend the definition concerning when an amendment is allowable under Article 123(2) EPC generally, but that it only sought a way of avoiding the potentially fatal consequences of the patentee being caught in the "inescapable trap" between the requirements of paragraphs (2) and (3) of Article 123 EPC (see point 13. of the Reasons).

Although the general principle expressed in that decision, namely that the purpose of Article 123(2) EPC is to avoid the applicant obtaining an unwarranted advantage by means of an amendment, is often cited and has also been relied on in later decisions of the Enlarged Board as being the purpose underlying Article 123(2) EPC, such later decisions have also made clear that the issue in question in decision <u>G 1/93</u> related to the conflicting requirements of Article 123(2) and (3) EPC and "hence, dealt with a completely different legal situation". This is how the Enlarged Board put it in its decision the disclosure test of G 3/89 was applied to the concept of the same invention.

Decision <u>G 1/03</u>, in point 2., penultimate paragraph of the Reasons, also starts from the premise that decision <u>G</u> 1/93 was concerned with the relationship between paragraphs (2) and (3) of Article 123 EPC. After having addressed the conflict identified in decision T 323/97 between decisions <u>G 1/93</u> and <u>G 2/98</u> with respect to the question of whether it matters that an added feature provides a technical contribution to the claimed subjectmatter, the Enlarged Board refrains from taking any position but ends by saying: "The question answered in T 323/97 in the negative is examined below in relation to the different situations arising in the present proceedings" (point 2. of the Reasons, last para.).

It can thus be stated that neither decision <u>G 1/93</u> nor decision <u>G 1/03</u> intended to modify the general definition of the requirements of Article 123(2) EPC established in opinion G 3/89 and decision G 11/91, which definition has become the generally accepted, one could also say the "gold" standard, for assessing any amendment for its compliance with Article 123(2) EPC. Therefore that definition also applies to the kind of cases underlying the present referral.

4.4 Is it to be derived from  $\underline{G \ 1/03}$  that the introduction of a disclaimer disclaiming disclosed subject-matter

cannot a priori modify the subject-matter remaining in the claim and that it is therefore always allowable?

Certain passages in this decision could be and indeed have been interpreted as expressing the Enlarged Board's position that introducing a disclaimer could a priori not change the technical information in the application and therefore not modify the subject-matter remaining in the claim.

4.4.1 The decision

In point 2.1.3 of the Reasons the Enlarged Board states after a detailed discussion of the legal history of Article 54(3) EPC (whole contents vs. prior claim approach) with respect to the question of a potential change of the content of technical information in the application by the introduction of a disclaimer:

"For the interpretation of Article 123(2) EPC, it may be concluded from the foregoing (point 2.1.1) that the purpose of a disclaimer excluding a conflicting application is merely to take account of the fact that different applicants are entitled to patents in respect of different aspects of inventive subject-matter and not to change the given technical teaching. The disclaimer splits the invention as a whole in two parts: ...

Such a disclaimer, only excluding subject-matter for legal reasons, is required to give effect to Article 54(3) EPC and has no bearing on the technical information in the application. It is, therefore, not in contradiction to Article 123(2) EPC. ... An invention comprising different specific embodiments or groups thereof has been disclosed in the application as filed, a part of which is excluded from the requested protection, i.e. no longer claimed. The remaining subject-matter is not modified by the disclaimer. ..."

In point 2.2.1 of the Reasons the Enlarged Board then states:

"The concept of accidental anticipation is akin to the situation of conflicting applications already discussed, starting from the premise that only novelty is at stake. In the case of an accidental anticipation, the exclusion of the unrelated state of the art is likewise not intended to contribute to the inventive merit of the technical teaching given."

4.4.2 Meaning of that jurisprudence

In order to assess correctly the statements cited in the foregoing, the context in which they were made as well as some further findings in this decision must be considered.

The context is first that in a preceding passage,

in point 2., second paragraph of the Reasons, the Enlarged Board had already dealt with and refuted the argument that a disclaimer is a mere voluntary restriction by which the applicant abandons part of the claimed subject-matter and that, therefore, the disclaimer per se is not a technical feature of the claim, cannot violate Article 123(2) EPC and should always be allowed. The Enlarged Board replied by stating that any amendment to a claim is presumed to have a technical meaning, otherwise it would be useless to have it in the claim. Hence, it appears that the proposition that disclaiming subject-matter could per se not change the content of technical information in the application and could therefore per se not violate Article 123(2) EPC, was not endorsed by the Enlarged Board of Appeal.

As a consequence, it appears that the purpose of the example given in point 2.1.3 of the Reasons of an invention comprising different specific embodiments or groups thereof disclosed in the application as filed, a part of which is excluded from the requested protection, must be understood as giving a typical example in which the disclaimer does not normally change the teaching of the subject-matter remaining in the claim and does not normally add information. It cannot be read as meaning that the Enlarged Board wished to establish the principle that an amendment to a claim by the introduction of a disclaimer disclaiming a disclosed embodiment could per se not modify the subject-matter remaining in the claim and could therefore never violate Article 123(2) EPC.

This is corroborated by the Enlarged Board's findings in points 2.6.2 and 2.6.5 of the Reasons. In point 2.6.2 the Enlarged Board speaks of "the principle that an undisclosed limitation has to be a mere disclaimer in the above sense" to be allowable. What is meant thereby is then further explained in point 2.6.5 of the Reasons, in which the Enlarged Board states:

"2.6.5 It results from the foregoing that a disclaimer may serve exclusively the purpose for which it is intended and nothing more. In the case of a disclaimer concerning conflicting applications, its purpose is to establish novelty with respect to a prior application in the sense of Article 54(3) EPC. In the case of a disclaimer concerning state of the art under Article 54(2) EPC, its purpose is to establish novelty vis-à-vis an accidental anticipation as defined in this decision. Finally, a disclaimer excluding subject-matter not eligible for patent protection may only serve the purpose of removing such specific legal obstacle. If a disclaimer has effects which go beyond its purpose as stated above, it is or becomes inadmissible."

It is true that these findings, in particular the last-cited sentence, are only embedded in the reasons for the decision and have not found their direct entrance into answer 2 in the order, setting out the criteria to be applied for assessing the allowability of an undisclosed disclaimer. That does not mean, however, that the above-cited findings were not made purposefully and need not be taken as meaning what is stated therein. The gist of the questions referred to the Enlarged Board in cases G 1/03 and G 2/03, on which the Enlarged Board had to give an answer, was to establish whether and, if so, under which circumstances undisclosed disclaimers could be considered allowable at all, as a matter of principle, despite the absence of a basis in the application as filed. It is this question and no more the Enlarged Board has answered in answer 2. The wording the Enlarged Board chose in the starting line of answer 2, reading "a disclaimer may be allowable" indicates that with the criteria set up in answer 2 the Enlarged Board did indeed not intend to give a complete definition of when a disclaimer violates Article 123(2) EPC and when it does not.

It is in this sense that the teaching of decision  $\underline{G 1/03}$  has also been interpreted first in decision T 1139/00 of 10

In decision T 1139/00, the Board, after having stated in point 2.5 of the Reasons that the subject-matter excluded by the disclaimer in question is supported by the application as filed, gives an extensive technical reasoning in points 3. and 4. (bearing the heading "Article 123(2) EPC") of the Reasons as to why the introduction of the disclaimer only limits the scope of protection "without providing any technical contribution to the invention as claimed" (point 3.1 of the Reasons), and why it only "leaves a more limited group" (point 4.1 of the Reasons, at the end). Thus, the Board did not consider Article 123(2) EPC as being automatically fulfilled as a consequence of the limitation having been performed by a disclaimer for disclosed subject-matter. In the decision handed down by the Court of Appeal of England and Wales cited above Jacob LJ states in point 82. of the Reasons, making reference to decision T 1139/00:

"<u>G 1/03</u> does not set up any further or more extensive rule than the basic rule that an undisclosed disclaimer is permissible as not adding matter provided it is a "mere disclaimer"."

In point 83. of the Reasons he then goes on, again with reference to decision T 1139/00: "So this TBA has held that  $\underline{G 1/03}$  is confined to novelty restoring or exclusion of unpatentable subject-matter disclaimers. It went on, rightly in our view, to address the real question: was there added subject-matter?"

And, in point 85. of the Reasons, by referring to the appealed decision: "Floyd J was entirely right when he said: [122] Nevertheless, the test for added subject matter remains that set out in the Convention and the Act...."

In the decision of the District Court of the Hague the Court also expressly endorses the finding in decision T 1139/00 that "the allowability of a "disclosed" disclaimer must be tested against Article 123 paragraph 2 of the EPC" and that it is "conceivable that the technical teaching of the patent changes if subject matter is excluded, which subject matter had initially been included in positive terms..." (points 4.14 and 4.15 of the Reasons).

#### 4.5 The criteria to be applied

## 4.5.1 The disclosure test

It is thus in accordance with the above-cited jurisprudence of the Enlarged Board and the national decisions that the principle that any amendment to an application or a patent, and in particular to a claim, must fulfil the requirements of Article 123(2) EPC also applies to an amendment limiting the claim by disclaiming disclosed subject-matter.

Therefore, as is the case for any other amendment, the test for an amendment to a claim by disclaiming subjectmatter disclosed as part of the invention in the application as filed must be that after the amendment the skilled person may not be presented with new technical information. Hence, disclaiming subject-matter disclosed in the application as filed can also infringe Article 123(2) EPC if it results in the skilled person being presented with technical information which he would not derive directly and unambiguously, using common general knowledge, from the application as filed.

4.5.2 How is the original disclosure of the claimed subject-matter to be determined with respect to a claim amended by the introduction of a disclaimer?

The critical question is how the original disclosure of the claimed subject-matter is to be determined in the case of the introduction into a claim of a disclaimer disclaiming disclosed subject-matter. If a positive feature, which defines subject-matter that is actually claimed, is introduced into a claim, it can be examined whether the subject-matter of that feature was disclosed in the application as filed. With respect to the new combination of features which is claimed after the introduction of that feature, it can be examined whether that is claimed after the introduction of that feature, it can be examined whether that combination was disclosed in the application as filed.

By contrast, the technical subject-matter defined in the disclaimer does not make the disclaimed subject-matter as such a part of the definition of the claimed invention. A disclaimer does not as such define a feature of the claimed invention. It is just the opposite. It defines something that is not claimed. Hence, when it comes to determining whether, after the introduction of the disclaimer, the claim infringes Article 123(2) EPC or whether it is in conformity with it, this cannot be decided solely by establishing that the disclaimed subject-matter is disclosed in the application as filed.

Whether the skilled person is presented with new information depends on how he or she would understand the amended claim, i.e. the subject-matter remaining in the amended claim and on whether, using common general knowledge, he or she would regard that subjectmatter as at least implicitly disclosed in the application as filed.

That statement corresponds to the definition given in Article 123(2) EPC. Transposed to the presently discussed issue of an amendment to a claim, Article 123(2) EPC would read:

"The claim may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed."

Hence, it follows from the wording of Article 123(2) EPC itself that the point of reference for assessing an amended claim for its compatibility with Article 123(2) EPC is the subject-matter which the claim contains after the amendment. In other words, it is the subject-matter remaining in the claim after the amendment.

# 4.5.3 Rules of logic

Whether that subject-matter was originally disclosed or not cannot be decided by following so-called rules of logic, in the sense that if an application discloses a general teaching and specific embodiments, groups thereof or areas, then all other potential embodiments, groups thereof or areas falling within the ambit of the general teaching (but not as such disclosed in the application as filed) would thereby, by implication, inevitably also be disclosed. In this context it was also submitted that the disclosure of an embodiment or smaller region (B) within a broader region (A), likewise disclosed, would thereby logically and inevitably disclose the subject-matter of the broader region minus the embodiment (A-B) and that a claim containing such a disclaimer would for that reason not contain subject-matter offending against Article 123(2) EPC.

Even if it may be said that there is not normally a problem with the original disclosure for the remaining subject-matter when originally disclosed specific embodiments, groups thereof or areas are disclaimed from the scope of a more general claim reflecting a more general teaching which has equally been disclosed, the question can nevertheless not be decided schematically. In particular, no principle can be acknowledged, which would be applicable a priori, to the effect that disclaiming disclosed specific embodiments, groups thereof or areas from a broader claim can never infringe Article 123(2) EPC. Also, no so-called rule of logic applies, in the sense that where an application discloses a general teaching and specific embodiments, groups thereof or areas, all other potential embodiments or intermediate generalisations falling within the ambit of the general teaching (but not as such disclosed in the application as filed) would thereby, by implication, inevitably also be disclosed. On the other hand, any schematic reasoning solely suggesting that the introduction of the disclaimer modifies the subjectmatter remaining in the claim because that amended claim contains less than the unamended claim, would also not be sufficient to motivate an objection under Article 123(2) EPC.

4.5.4 Need for technical assessment of the case under consideration

Instead, what is required is an 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.

The test to be applied is whether the skilled person would, using common general knowledge, regard the remaining claimed subject-matter as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed.

This test is the same as that applied when the allowability of a limitation of a claim by a positively defined feature is to be determined. In this respect a whole body of jurisprudence exists, in particular with respect to cases in which the limitation could lead to the singling out of compounds or sub-classes of compounds or other so-called intermediate generalisations not specifically mentioned nor implicitly disclosed in the application as filed (see Case Law of the Boards of Appeal of the European Patent Office, sixth edition, July 2010, III.A.1. and 2.). The principles of that jurisprudence can and must be applied in the same manner to amendments of claims by disclaiming disclosed specific embodiments, groups thereof or areas as they apply to limitations performed by positively defined features.

IPPT20110830, EBA-EPO, Disclaimer

Where, for instance, as was said in decision  $G \frac{1}{03}$ (point 2.1.3 of the Reasons), in the application as filed an invention has been disclosed and claimed in general terms and different specific embodiments or groups thereof have also been disclosed, and one of these is later excluded from the requested protection by the disclaimer, the remaining subject-matter, i.e. the remaining general teaching, will normally not be modified by the disclaimer. This contrasts with the situation in which, for instance, the disclaimer would have the effect of confining the subject-matter remaining in the claim to a subgroup of the originally claimed subject-matter, which subgroup could not be regarded as disclosed in the application as filed, even taking into account what the skilled person, using common general knowledge, would regard as implicit in the contents of the application as filed. In this case the amendment would contravene Article 123(2) EPC. By analogy with decision T 615/95, there would be added matter where the insertion of a disclaimer into a claim would result in singling out any hitherto not specifically mentioned or at least implicitly disclosed individual compound or group of compounds, or would lead to a particular meaning of the remaining claimed subject-matter which was not originally disclosed.

4.5.5 The relevance of the fact that the disclaimed subject-matter is disclosed as part of the invention

Decision T 1102/00 and other decisions following the same approach have put forward as a reason for not allowing the disclaiming of subject-matter disclosed in the application as filed that that subject-matter was not presented in the application as filed as subject-matter to be excluded from protection, but on the contrary as part of the invention. That line of reasoning does not hold good.

It is in principle for the applicant to determine the scope of protection he desires by the manner in which he drafts his claims. There is no provision in the EPC which would oblige an applicant to seek, in the individual application protection under consideration, а corresponding to the broadest possibility offered by the disclosure of the application. Nor is there an obligation to draft claims in such a way as to include the preferred embodiment in their scope. To amend a claim in a way excluding disclosed subject-matter from it, in particular when by disclaiming a preferred embodiment, is at the applicant's risk because it is clear that when it comes to determining whether the amended claim fulfils the remaining requirements of the EPC, such as support by the description (Article 84 EPC), sufficiency of disclosure (Article 83 EPC) and inventive step (Article 56 EPC), the disclaimed subject-matter cannot be taken into account. In respect of inventive step the questions as to whether the problem has been solved over the whole breadth of the claim or whether an advantageous effect obtained by the remaining claimed subject-matter can be deduced from the application as filed may in particular become relevant.

With this proviso, i.e. subject to the claimed subjectmatter fulfilling the requirements of the EPC, the applicant is free, i.e. he is entitled, not to claim protection for an embodiment or even a part of the disclosed invention. The applicant may, for example, be interested in obtaining a first quicker protection for a preferred embodiment and pursue the general teaching in a divisional application. Whether or not and, if so, under what circumstances, in such a case a disclaimer would be necessary in order to avoid the so-called prohibition on double protection is a different matter. It is sufficient to say that such procedural behaviour is not abusive and even legitimate. The amici curiae also mentioned other possible reasons not related to the requirements for patentability for splitting an application up into different applications for different embodiments, for instance for licensing purposes.

Taking it to the extreme, if the idea were correct that a disclosed embodiment of the invention could not be disclaimed because it was presented in the application as part of the invention, then as a result no limiting amendment of a claim would be possible at all, since even in the case of a limitation by positively defined features the situation is that through this limitation something is excluded from the claim which was previously presented as being part of the invention. If by contrast, an embodiment is presented in the application as filed as not being part of the invention, but e.g. as belonging to the state of the art or as a comparative example, then it cannot be claimed at all.

To conclude, no convincing reason has been advanced for not applying the principles developed in the context of Article 123(2) EPC for the assessment of amendments to claims by the introduction of positive limiting features in the same manner to limitations of claims by disclaimers which disclaim subject-matter disclosed in the application as filed.

4.6 Coherence of the approach with other issues relating to disclosure

Such an approach does not distort, but rather preserves, the structural relationship established in the EPC, based on the first-to-file system, between the provisions defining the state of the art and their impact on patentability, the substantive requirements for validly claiming a priority (concept of same invention) or for the filing of divisional applications and for the right to amend the application. It is vital that a uniform concept of disclosure is applied in all these respects and that the rights of an applicant are uniformly determined in all these contexts as extending to but at the same time as being limited to the disclosure made at the relevant point in time. This was emphasised in decision G 2/98, in which, in the context of determining the right to priority derivable from an application, the Enlarged Board endorsed a narrow or strict interpretation of the concept of "the same invention", limiting the right to priority to subject-matter which the person skilled in the art can derive directly and unambiguously, using common general knowledge, from the previous application as a whole (point 9. of the Reasons). In that decision the Enlarged Board also emphasised that any concept other than making the entitlement to priority dependent on the disclosure of the priority document could undermine patent protection for selection inventions, and held: "Hence, such priority claims should not be acknowledged if the selection inventions in question are considered "novel" according to these criteria" (point 8.4 of the Reasons). The same must apply to any amendment of an application under Article 123(2) EPC. It may not create novel subject-matter.

The importance of applying a uniform concept of disclosure was again confirmed in decision <u>G 1/03</u> (point 2.2.2 of the Reasons), where the Enlarged Board emphasised that "the European Patent System must be consistent and the concept of disclosure must be the same for the purposes of Articles 54, 87 and 123 EPC". Accordingly, it appears that the approach, as adopted here with regard to the requirements to be met in order for amendments by the introduction of disclaimers for disclosed subject-matter to be allowable under Article 123(2) EPC does not lead to an unjustified result as compared with any of the above mentioned matters.

Nor does this approach impair an applicant's right under Article 76(1) EPC to divide the application and split its subject-matter up into different applications, since according to Article 76(1), second sentence, EPC that right is in any case limited to the subject-matter which can be regarded as being disclosed in the earlier (the parent) application as filed (the "root" application in case of a sequence of divisional applications, see decisions  $\underline{G}$ 1/05 and G 1/06, OJ EPO 2008, 271 and 307). Therefore, if the subject-matter of a claim in a divisional application, in which an embodiment disclosed in the parent application is disclaimed, cannot be regarded as at least implicitly disclosed in the parent (or root application in the case of a sequence of divisional applications), because the disclaimer has the effect of confining the subject-matter remaining claimed in the divisional application to something which can not be regarded as disclosed in the parent or root (as the case may be) application as filed, then there is no right to file a divisional application in respect of that subject-matter. The same considerations govern the entitlement to the priority of an earlier application claimed in a later application in which a disclaimer is introduced disclaiming subject-matter disclosed in the priority application.

Finally, the same also applies under Article 61(1)(b) EPC if the entitled person files a new application and the original application must be confined to the subject-matter to which the original applicant remains entitled. As with any amendment, such an amendment is also subject to the requirements of Article 123(2) EPC. This means that where a limitation of the original application is made by introducing a disclaimer, this is only allowable to the extent that the subject-matter remaining in the claim after such limitation can be regarded as disclosed in the application as filed.

#### 4.7 The President's suggestion

The President has suggested in footnote 28 to his submissions that where the subject-matter remaining in the claim is not directly and unambiguously derivable from the application as filed, the criteria established in decision <u>G 1/03</u> should be applied regarding the allowability of the disclaimer.

The Enlarged Board fails to see any justification for adopting such an approach. As can be derived from the Enlarged Board's position developed in the foregoing, in accordance with the principles developed in the above cited earlier rulings of the Enlarged Board, the overriding principle for any amendment to be allowable under Article 123(2) EPC is that the subject-matter of an amended claim must be at least implicitly disclosed to the skilled person, using common general knowledge, in the application as filed. As has also been set out in the foregoing that applies equally to the subject-matter of a claim the scope of which is determined by a disclaimer. Where this requirement is not fulfilled in the individual case under consideration because the effect of the disclaimer is to limit the claim to subject-matter, such as a subgroup, an intermediate generalisation or else, which cannot be regarded as disclosed in the application as filed, then there is no justification for granting a patent on such a claim. As has also been set out previously, any other view would undermine the legal system of the EPC based on the first-to-file principle and in particular the patentability of selection inventions.

In the oral proceedings before the Enlarged Board the representative of the President explained why the additional application of the criteria established in answer 2 of decision  $\underline{G \ 1/03}$  to the allowability of a disclaimer for disclosed subject-matter not having passed the remaining subject-matter test under Article 123(2) EPC had been suggested. This was because otherwise, in the case of a state of the art according to Article 54(3) EPC, an applicant disclaiming disclosed subject-matter could be in a worse position than an applicant disclaiming subject-matter for which there was no disclosure in his application. This was so since according to decision G 1/03 in the latter case the applicant did not have to show that the subject-matter remaining in the claim after the introduction of the disclaimer was also disclosed as such in the application as filed.

The Enlarged Board does not hold this discrepancy to exist. It does not interpret decision  $G \frac{1}{03}$  to have intended, in its answer 2, to exhaustively determine the conditions under which, if fulfilled, an amendment by introduction of an undisclosed disclaimer was to be regarded as allowable under Article 123(2) EPC under all circumstances. As has already been set out in point 4.4.2 above, the gist of the questions referred to the Enlarged Board in cases G 1/03 and G 2/03, to which the Enlarged Board had to give an answer, was to establish whether and, if so, under which circumstances undisclosed disclaimers could be considered allowable at all, as a matter of principle, despite the absence of a basis in the application as filed. It is this question and no more the Enlarged Board has answered in answer 2. The wording the Enlarged Board chose in the starting line of answer 2, reading "a disclaimer may be allowable", indicates that with the criteria set up in answer 2 the Enlarged Board did indeed not intend to give a complete definition of when an undisclosed disclaimer violates Article 123(2) EPC and when it does not.

Hence, in that decision it was not decided that, the requirements of answer 2 being fulfilled, an undisclosed disclaimer would be always allowable under Article 123(2) EPC.

# ORDER

For these reasons it is decided that:

The question referred to the Enlarged Board of Appeal is answered as follows:

1a. An amendment to a claim by the introduction of a disclaimer disclaiming from it subject-matter disclosed in the application as filed infringes Article 123(2) EPC if the subject-matter remaining in the claim after the introduction of the disclaimer is not, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.

1b. Determining 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.

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