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Datasheet for the decision of 10 September 2025

Case Number: T 1894/23 - 3.3.08

Application Number: 15783300.5

Publication Number: 3134551

IPC: C12Q1/6844, C12Q1/6853

Language of the proceedings: EN

Title of invention:
Compositions and methods for enhancing and/or predicting DNA amplification

Patent Proprietor:
Envirologix Inc.

Opponent:
Mathys & Squire LLP

Headword:
DNA amplification/ENVIROLOGIX

Relevant legal provisions:
EPC Art. 54, 112(1)(a)
RPBA 2020 Art. 12(4), 12(6)

Keyword:

Novelty - (no)
Referral to the Enlarged Board of Appeal - (no)
Amendment to case - requirements of Art. 12(2) RPBA 2020 met (no)
Late-filed request - should have been submitted in first-instance proceedings (yes)

Decisions cited:

T 1480/16, T 0981/17, T 1569/17, T 0306/18, T 0494/18, T 0995/18, T 1151/18, T 2080/18, T 2091/18, T 2243/18, T 0482/19, T 1792/19, T 2201/19, T 2019/20, T 1800/21

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Case Number: T 1894/23 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 10 September 2025

Appellant: (Opponent)	Mathys & Squire LLP The Shard 32 London Bridge Street London SE1 9SG (GB)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Respondent: (Patent Proprietor)	Envirologix Inc. 500 Riverside Industrial Parkway Portland, Maine 04103 (US)
Representative:	Grund, Martin Grund Intellectual Property Group Patentanwälte und Solicitor PartG mbB Steinsdorfstraße 2 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 31 August 2023 concerning maintenance of the European Patent No. 3134551 in amended form**

Composition of the Board:

Chairwoman	R. Morawetz
Members:	A. Schmitt
	L. Bühler

Summary of Facts and Submissions

I. The appeal lodged by the opponent (appellant) is against the opposition division's interlocutory decision concerning the maintenance of European patent No. 3 134 551 (the patent) as amended on the basis of auxiliary request 7 filed on 16 May 2023.

II. The patent was granted on the basis of European patent application No. 15 783 300.5, which had been filed as an international application published as WO 2015/164494 (the application) and claiming priority from US application No. 61/982,784 (P1).

III. The opposition proceedings were based on the grounds for opposition under Article 100(a) EPC in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and on those under Article 100(b) and (c) EPC.

IV. With the reply to the appeal, the patent proprietor (respondent) submitted sets of claims of a main request and auxiliary requests 1 to 41.

V. In a further submission dated 20 May 2025, the appellant commented on, *inter alia*, the admittance of auxiliary requests 1 to 41.

VI. The board summoned the parties to oral proceedings in accordance with their requests and, in a communication under Article 15(1) RPBA, expressed its preliminary opinion on some of the matters raised.

VII. Both parties made a further submission commenting on, *inter alia*, the admittance of auxiliary request 36.

VIII. During the oral proceedings, the respondent renumbered auxiliary request 36 as auxiliary request 1 and auxiliary requests 1 to 35 as auxiliary requests 2 to 36 and requested that the following question be referred to the Enlarged Board of Appeal: "*In appeal proceedings, is the deletion of a claim category from a request decided upon by the opposition division admissible if filed with the first submission during appeal proceedings?*"

IX. Claim 1 of the main request reads as follows:

"1. An isolated primer oligonucleotide comprising from 5' to 3',
i) a first region comprising a self-complementary sequence comprising from 5' to 3' the reverse complement of a nicking enzyme recognition sequence, a palindromic sequence, and said nicking enzyme recognition sequence, wherein said first region is fully self-complementary, and
ii) a second region at least 16 nucleotides long that specifically binds to a complementary region on a target nucleic acid molecule to form a double-stranded primer-target hybrid having a ΔG that is at least 62.76 kJ/mol (15 kcal/mol) lower than the ΔG of a self-dimer comprising the second region of the primer, wherein the second region comprises at the 3' end one or more 2' modified nucleotides,
with the proviso that said isolated primer oligonucleotide is not selected from the group consisting of:
[...]."

X. Claim 1 of auxiliary request 1 reads as follows:

"1. A method of amplifying a specific product in a nicking and extension amplification reaction, the method comprising:
(a) contacting a target nucleic acid molecule under substantially isothermal conditions with a polymerase, two or more primers, each of which specifically binds to a complementary sequence on the target nucleic acid molecule, a nicking enzyme, and a detectable polynucleotide probe, wherein at least one primer comprises from 5' to 3',
i) a first region comprising a self-complementary sequence comprising from 5' to 3' the reverse complement of a nicking enzyme recognition sequence, a palindromic sequence, and said nicking enzyme recognition sequence, and
ii) a second region at least 16 nucleotides long that specifically binds to a complementary region on a target nucleic acid molecule to form a double-stranded primer-target hybrid having a ΔG that is at least 62.76 kJ/mol (15 kcal/mol) lower than the ΔG of a self-dimer comprising the second region of the primer, wherein the second region comprises at the 3' end one or more 2' modified nucleotides; and
(b) generating amplicons comprising at least a portion of said target nucleic acid molecule,
with the proviso that:
(i) the method is not a method of [...]; and
(ii) the method is not a method of [...]."

Claim 2 of auxiliary request 1 concerns a method of detecting a specific product in a nicking and extension amplification reaction, the method comprising, *inter alia*, contacting a target nucleic acid molecule under substantially isothermal conditions with a polymerase,

two or more primers, each of which specifically binds to a complementary sequence on the target nucleic acid molecule, a nicking enzyme, wherein at least one primer comprises from 5' to 3' a first region and a second region as defined in items i) and ii) of claim 1 of auxiliary request 1 (see above).

XI. The following documents are referred to in this decision:

D5 WO 2013/155056 A1
D21 Affidavit by Prof. John Santalucia

XII. The parties' submissions and arguments, in so far as they are relevant to the present decision, are summarised and discussed in "Reasons for the Decision".

XIII. Requests of the parties in so far as relevant to the present decision:

The appellant requests that the decision under appeal be set aside, that the patent be revoked and that auxiliary requests 1 to 41 not be admitted into the appeal proceedings.

The respondent requests that the appeal be dismissed, i.e. that the patent be maintained as amended on the basis of auxiliary request 7 considered by the opposition division (main request), or, in the alternative, that the patent be maintained as amended on the basis of the set of claims of one of auxiliary requests 1 to 41, submitted with the reply to the appeal as auxiliary requests 36, 1 to 35 and 37 to 41.

The respondent further requested that the following question be referred to the Enlarged Board of Appeal:

"*In appeal proceedings, is the deletion of a claim category from a request decided upon by the opposition division admissible if filed with the first submission during appeal proceedings?*"

Reasons for the Decision

Main request
Claim construction – claim 1

1. Claim 1 concerns an isolated primer oligonucleotide comprising from 5' to 3'
i) a first region comprising a self-complementary sequence comprising from 5' to 3' the reverse complement of a nicking enzyme recognition sequence, a palindromic sequence, and said nicking enzyme recognition sequence, wherein said first region is fully self-complementary, and
ii) a second region at least 16 nucleotides long that specifically binds to a complementary region on a target nucleic acid molecule to form a double-stranded primer-target hybrid having a ΔG that is at least 62.76 kJ/mol (15 kcal/mol) lower than the ΔG of a self-dimer comprising the second region of the primer, wherein the second region comprises at the 3' end one or more 2' modified nucleotides (see section IX. above).

The first region

2. Since the primer oligonucleotide is defined as "comprising" a first and a second region, the board

concurs with the appellant that the primer oligonucleotide can comprise additional undefined nucleotides at the 5'-end of the first region and at the 3'-end of the second region. Hence, contrary to the respondent's assertion, the claimed primer oligonucleotide does not necessarily start, at its 5'-end, with the first region, but rather may start with one or more nucleotides that are not part of the first region.

3. This view is not changed by the additional requirement expressed in the claim that the first region is "fully self-complementary". The use of this expression only means that the first region does not comprise any nucleotides 5' or 3' of or between the three elements defined in the claim (the reverse complement of a nicking enzyme recognition sequence, a palindromic sequence, the nicking enzyme recognition sequence) that are not self-complementary. This feature thus affects the sequence of the first region with respect to any undefined elements and its 5'- and 3'-boundaries. However, it does not have any influence on the meaning of the term "comprising" in the preamble of the claim and does not mean that the first region must start at the 5'-end of the primer oligonucleotide.

4. In view of this, any part of a primer oligonucleotide that is a) 5' of a second region, b) is fully self-complementary and c) consists, from 5' to 3', of the reverse complement of a nicking enzyme recognition region, a palindromic sequence and the nicking enzyme recognition region falls under the definition of the first region in item i) of the claim, irrespective of whether the primer oligonucleotide comprises additional nucleotides 5' of this region.

5. The respondent contested this view, asserting that the claim wording that the primer oligonucleotide comprised "*from 5' to 3' a first region*" excluded the possibility of the primer containing additional nucleotides 5' of this first region. The expression "from 5' to 3'" indicated the 5'-end of the primer, meaning that the "first" region started at this 5'-end. This was also clear from claim 6 of the patent as granted, which contained an option for the first region to be "fully self-complementary". In the appellant's claim construction, this feature of claim 6 of the patent as granted would be redundant.

6. This line of argument is not persuasive because, as pointed out in point 2. above, the claim defines the primer oligonucleotide as "*comprising*" from 5' to 3' a first and a second region. The use of the term "comprising" undoubtedly allows for the presence of additional nucleotides, including 5' of the first region. Denoting the regions defined in the claim as "first" and "second" region cannot change this commonly accepted meaning of the term "comprising". Hence, the expression "from 5' to 3'" in combination with the term "comprising" merely indicates the order of the first and second region in the primer oligonucleotide. It does not mean either that the first region must start at the 5'-end of the primer oligonucleotide or, as a consequence, that the first nucleotide of the primer oligonucleotide at the 5'-end necessarily has to be part of the first region.

7. Moreover, as already explained in point 3. above, the feature that the first region is "fully self-complementary" means that the first region, which is defined as *comprising* a self-complementary sequence *comprising* the reverse complement of a nicking enzyme

recognition sequence, a palindromic sequence and the nicking enzyme recognition sequence, cannot comprise any nucleotides 5' or 3' of or between any of these three elements that are not self-complementary. The primer oligonucleotide of claim 1 of the patent as granted undoubtedly encompassed at least the first two options given that the first region in this claim *comprises* a self-complementary region that *comprises* from 5' to 3' the three elements listed. Consequently, even in the appellant's claim construction endorsed by the board, claim 6 as granted restricted the ambit of the claim compared with claim 1 of the patent as granted and was therefore not redundant.

The second region

8. The second region as defined in the claim has a length of at least 16 nucleotides, specifically binds to a complementary region on a target nucleic acid molecule to form a double-stranded primer-target hybrid, and comprises at the 3' end one or more 2' modified nucleotides. The "target" nucleic acid molecule to which the claim refers is not further defined. Since every nucleic acid sequence with a length of 16 nucleotides specifically binds to its complementary "target" sequence to form a double-stranded hybrid, the reference to a "target" nucleic acid in the claim does not in any way limit the nucleic acid sequence of the second region. Instead, it merely designates the complementary sequence of the part of the oligonucleotide primer that is or can be defined as the second region.

9. The claim also requires that the second region forms a double-stranded primer-target hybrid having a ΔG (free energy) that is at least 62.76 kJ/mol (15 kcal/mol)

lower than the "*ΔG of a self-dimer comprising the second region of the primer*" (emphasis added by the board). Hence, contrary to the respondent's assertion, the claim does not require the ΔG of the primer-target hybrid to be compared with the ΔG of the most stable self-dimer. Rather, it may be compared with the ΔG of any self-dimer formed by the second region, including the least stable one. Additionally, the ΔG depends on, *inter alia*, the temperature, the salt concentration and the pressure, none of which are defined in the claim.

10. To assess whether or not a given nucleic acid sequence of at least 16 nucleotides fulfils the requirement that the ΔG of a double-stranded primer-target hybrid is at least 15 kcal/mol lower than the ΔG of a self-dimer comprising the second region of the primer, the skilled person can use any of the conditions and variables listed above (point 9.), including comparing the ΔG of the second region hybridised to its complementary sequence with that of the least stable self-dimer formed by the second region.

11. The respondent asserted that the contention that the difference in ΔG, i.e. the ΔΔG value of the second region, could be calculated on the basis of any self-dimer of the second region instead of the most stable self-dimer had been raised for the first time in the statement of grounds of appeal and therefore should not be admitted into the proceedings. However, the appellant is right in that this argument on claim construction had already been presented in the notice of opposition and thus had not been newly filed on appeal.

12. This is evident from sections 6.18 and 7.13 of the notice of opposition. In section 6.18, the appellant

submitted that the expression "a self-dimer comprising the second region of the primer" used in the claim was not identical to the expression "the most stable self dimer of region 2" used in the priority document P1, but, instead, "*self-evidently encompasse*[d] *dimers which are not the most stable*". In section 7.13, the appellant argued that the claims were "*silent as to which self-dimer construct (of which there are typically a large number) should be used for this comparison*" and that the wording of the claim allowed for a "*comparison with other, less-stable dimers*".

13. Hence, this line of argument raised in the opposition proceedings forms part of the appeal proceedings and is taken into account by the board. To fulfil the requirement expressed in the claim, the ΔG of the double-stranded primer-target hybrid need only be at least 62.76 kJ/mol (15 kcal/mol) lower than the ΔG of the least stable self-dimer comprising the second region of the primer.

Novelty (Article 54(2) EPC) – claim 1
Document D5

14. Document D5 discloses (Figure 1) a primer with the nucleic acid sequence
5' **T**GACTCCATATGGAGTC***A****CATGGTTCATmUmCmGmUmG*** 3'
(primer P19 in the parties' denotation; emphasis added by the board). The two underlined sequences are the reverse complement of a nicking enzyme recognition sequence (GACTC) and the nicking enzyme recognition sequence (GAGTC) and are separated by a palindromic sequence (CATATG). This part of primer P19 corresponds to the first region as defined in the claim. The subsequent 16 nucleotides shown in italics form a "second region" as defined in the claim that

specifically binds to its complementary sequence and comprises at its 3'-end five 2'-O-methyl modified nucleotides shown as mX (D5, page 13, lines 13 to 17).

15. The respondent asserted that the primer P19 did not comprise a "second region" of 16 nucleotides in length for two reasons. Firstly, the first nucleotide at the alleged 5'-end of the second region as defined by the appellant (an A, shown in bold above) was in fact part of the first region as it was complementary to the first nucleotide of the primer oligonucleotide at its 5'-end (a T, shown in bold above), and so only 15 nucleotides of the primer P19 could be considered a potential "second region". Secondly, the primer P19 was used in D5 to amplify a bacterial target DNA, and only 11 nucleotides of these 15 nucleotides were complementary to this target DNA. Moreover, if the ΔΔG value were calculated on the basis of this partially complementary "second region" of 15 nucleotides, it would be less than 15 kcal/mol (section 3.8.4 and Table 1 of D21). Primer 19 therefore did not fulfil the requirement of a ΔΔG of at least 15 kcal/mol either.

16. However, as established above (see points 2. to 4.), the claim does not require the first region to necessarily start at the 5'-end of the primer oligonucleotide. Since nucleotides 2 to 17 of primer P19 shown above fulfil all the requirements set out in the claim for the first region (see point 14. above), the board cannot agree with the respondent's first line of argument that the 1st and 18th nucleotides of the oligonucleotide primer were also part of its first region. Nucleotides 2 to 17 of primer P19 therefore form a "first region" as defined in the claim, and

primer P19 also comprises a "second region" 3' of this first region which is 16 nucleotides long.

17. Furthermore, since the target nucleic acid sequence is neither structurally nor functionally defined in the claim, it is not limiting (see also point 8. above), meaning that the intended target of a primer disclosed in a prior-art document is irrelevant for assessing whether this primer falls within the ambit of product claim 1. The respondent's second argument that the second region of primer P19 was only partially complementary to its target is therefore not persuasive either. Consequently, the ΔΔG value of the "second region" of the P19 primer as identified in point 14. above can be calculated on the basis of a target sequence that is fully complementary to the 16 nucleotides of this region. As demonstrated by the appellant – and not contested by the respondent – the calculated ΔΔG value for this second region is less than 15 kcal/mol (section 80 of the statement of grounds of appeal).

18. The subject-matter of claim 1 is not novel over primer P19 disclosed in document D5 (Article 54 EPC).

Auxiliary request 1
Admittance (Article 12(4) and (6) RPBA)

19. Auxiliary request 1 was filed with the reply to the appeal as auxiliary request 36 to address an allegedly new objection raised by the appellant under Article 56 EPC against the product claims (section 122 of the reply to the appeal). However, it was then renumbered as auxiliary request 1 and relied on to address the lack of novelty of the main request.

20. The set of claims of auxiliary request 1 is identical to the set of claims of the main request (auxiliary request 7 considered in the decision under appeal) except that the product claims 1, 2 and 11 and any references to these claims in the dependent claims were deleted and the remaining claims and claim references renumbered accordingly. Hence, the set of claims of auxiliary request 1 contains two independent claims directed to methods (claims 1 and 2; see section X. above).

21. The respondent did not contest that a claim request containing only method claims had never been submitted during the opposition proceedings and that auxiliary request 1 was new to the proceedings. However, the respondent asserted that deleting entire claim categories from a previously filed request was not an amendment to its case.

22. The board cannot accept this line of argument. Under Article 12(4) RPBA, an amendment is a submission in the statement of grounds of appeal or in the reply to the appeal which is not directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based (Case Law of the Boards of Appeal of the European Patent Office, 11th edition, 2025 ("CLBA"), V.A.4.2.2(a)). The opposition division decides on the admissibility and the allowability of claim requests as a whole. Therefore, a set of claims that has never been submitted during opposition proceedings cannot be a request on which the decision under appeal is based (Article 12(2) RPBA).

23. Consequently, a set of claims which is filed for the first time on appeal constitutes an amendment to the case within the meaning of Article 12(4) RPBA, even if

the request differs from a request decided upon in the decision under appeal merely on account of an entire claim category being deleted.

24. The respondent contested this formalistic interpretation of Article 12 RPBA, arguing that the opposition division had found auxiliary request 7 to meet the requirements of the EPC. Since this request included the method claims of auxiliary request 1, the opposition division had necessarily taken a decision on the allowability of these method claims. The respondent even seemed to be of the view that there was a decision on the method claims which the appellant should have addressed in its statement of grounds of appeal.

25. The board disagrees. As conceded by the respondent, the opposition division had never given specific reasons for the patentability of the method claims even though the corresponding claims of the patent as granted had been opposed. Rather, the opposition division appears to have derived its decision on the novelty and inventive step of the method claims from its finding that the claimed product was novel and inventive (see point 36. below). Therefore, there is no stand-alone decision by the opposition division on the allowability of the method claims that is independent of its findings for the product claims.

26. Since the opposition division's decision with regard to the product claims did not stand up to review by the board (see main request above), the reasons given in the decision cannot support the patentability of the method claims any longer. Therefore, examining their allowability would require novelty and inventive step to be re-assessed, implying a change of the legal and factual framework of the appeal (T 1480/16,

Reasons 2.3; T 482/19, Reasons 5.7; T 1569/17, Reasons 4.3.4). Therefore, auxiliary request 1 also amounts to a amendment to the respondent's case in substance.

27. The respondent further relied on a series of decisions with regard to Article 13(1) and (2) RPBA according to which deleting a claim category, dependent claims or alternatives within claims was not considered an amendment to the patent proprietor's appeal case. The respondent argued that this approach *a fortiori* had to apply to claim requests filed at the beginning of the appeal proceedings.

28. The board disagrees. It is correct that several decisions (e.g. T 1480/16, Reasons 2.3; T 981/17, Reasons 3; T 995/18, Reasons 2; T 1151/18, Reasons 2; T 2243/18, Reasons 2; T 1792/19, Reasons 2; T 2201/19, Reasons 5.5) have held that an appeal case has not been amended where deleting claims present in a previously filed set of claims did not alter the factual and legal framework of the case or the subject of the discussions or entail re-evaluating the matters at issue. However, as explained above, in the case in hand there is no stand-alone decision by the opposition division on the method claims, nor any discussion of the appellant's objections raised in the opposition proceedings against the method claims. In that respect, the circumstances in this appeal are fundamentally different from those underpinning the above decisions and do not fulfil the conditions established in those decisions.

29. Moreover, more recent decisions have predominantly held that deleting claims present in a previously filed set of claims is to be regarded as an amendment to a party's appeal case within the meaning of

Article 13 RPBA in line with e.g. T 494/18, Reasons 1.3 and T 2091/18, Reasons 4. The diverging approaches seem to be converging towards the majority opinion (see in particular T 1800/21, Reasons 3.3 and 3.4 and decisions cited in that decision).

30. The admittance of auxiliary request 1, as an amendment to the respondent's case, is therefore at the board's discretion (Article 12(4) RPBA).

31. Under Article 12(6), second sentence, RPBA, the board should, in principle, not admit, *inter alia*, requests which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance. It is well established in the case law of the boards of appeal that Article 12(6), second sentence, RPBA expresses and codifies the principle that each party should submit all facts, evidence, arguments and requests that appear relevant as early as possible to ensure a fair, speedy and efficient procedure (CLBA, V.A.4.3.7(a)).

32. In the case in hand, the respondent relied on auxiliary request 1 to address novelty objections against the claimed products. However, these objections had been raised from the outset of the opposition proceedings. In view of this, the board cannot discern any persuasive reasons why this claim request was not filed in the opposition proceedings, or any circumstances of the appeal that would justify filing this request only on appeal. The respondent did not furnish any either.

33. The respondent asserted that auxiliary request 1 should nevertheless be admitted since its filing constituted exceptional circumstances even under the restrictive

conditions of Article 13(2) RPBA. The reason for this was the same as when contesting an amendment to the case within the meaning of Article 12(4) RPBA, namely that the method claims of auxiliary request 1 were identical to the method claims examined and decided upon with respect to all patentability requirements by the opposition division in previous auxiliary request 7. All the claims of auxiliary request 1 had thus been discussed in the opposition proceedings and upheld by the opposition division.

34. According to the respondent, auxiliary request 1 therefore did not constitute a change in scope of the appeal proceedings, did not raise any new issues, addressed the novelty objection raised against the product claims and was neither surprising nor disadvantageous to the appellant. Not admitting auxiliary request 1 would violate established case law of the boards of appeal under which limiting a previously filed request to certain independent claims was admissible on appeal (T 306/18, Reasons 5.1.4; T 2080/18, Reasons 5.1.3; T 1800/21, Reasons 3.4.3 and 3.4.4); T 2019/20, Catchword).

35. However, these arguments are not convincing. The board agrees that the question of whether and to what extent an amended set of claims changes the legal and factual framework of the appeal is a consideration relevant in the exercise of discretion under Article 12(4) RPBA. The criteria to be taken into account in the exercise of discretion referred to in this provision are the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal and the need for procedural economy. However, as set out above, Article 12(6) RPBA should be taken into account too. As the appellant

correctly pointed out, it had attacked both the product and the method claims in the opposition proceedings. Despite this, the respondent filed 15 amended claim requests during the opposition proceedings, including some in which the method claims were deleted but not a single one in which the product claims were deleted. The appellant is therefore right that admitting current auxiliary request 1 would shift the focus and scope of the proceedings from the product to the method claims on appeal.

36. The appellant is also right that, contrary to the respondent's view, the opposition division did not provide a substantive decision specifically on the claimed methods. Instead, after considering that the claimed primer oligonucleotides were novel, the opposition division held that the subject-matter of auxiliary request 7 was inventive over document D5 alone or in combination with D19 because the design, production and use of a primer comprising first and second regions as defined were not obvious (section 1 on page 13 and sections 3, 3.1 and 3.2 on page 14 of the decision under appeal). Hence, the decision under appeal only considered the patentability of the claimed primer oligonucleotides. The claimed methods were found inventive solely by virtue of the primer oligonucleotides they used.

37. Since the board's construction of the product claims and, as a result, its assessment of the novelty of these claims differ from the opposition division's, the distinguishing features are different, and thus so too is the discussion of inventive step. The opposition division's opinion on the novelty and inventive step of the oligonucleotide primers is thus not directly applicable to the method claims of auxiliary request 1.

38. In addition, as pointed out by the appellant, the primer oligonucleotides used in the method claims are not the same as those defined in the product claims decided upon by the opposition division. The appellant is therefore right that a new focus on the method claims potentially raises new issues since arguments directed to claims which were not substantively addressed in the decision under appeal would need to be discussed. Contrary to the respondent's view, auxiliary request 1 therefore could not be dealt with on appeal simply by reviewing the opposition division's decision on inventive step issued with respect to the product claims. The appellant is also right that admitting auxiliary request 1 would not simplify the proceedings or be in keeping with procedural economy.

39. Contrary to the respondent's assertion, the objection that the primers in the product and the method claims were defined differently and might have different consequences for the assessment of inventive step was indeed raised in the opposition proceedings; see the fourth and seventh paragraphs on page 5 of the minutes of the oral proceedings before the opposition division. It is therefore not a new line of argument and is taken into account on appeal.

40. Lastly, for the reasons set out above (point 32.), current auxiliary request 1 could have been filed during the opposition proceedings. For want of any such claim request filed during the opposition proceedings, there was no reason for the appellant to anticipate the filing of such a set of claims on appeal. Shifting the focus to the claimed methods only on appeal is therefore surprising for the appellant.

41. In view of the above considerations, the board decided not to admit auxiliary request 1 into the proceedings under Article 12(4) RPBA and Article 12(6) RPBA as this claim request addresses novelty objections against the product claims that had been raised at the outset of the proceedings. Auxiliary request 1 therefore should have been filed in the opposition proceedings. Moreover, admitting this request would neither simplify the proceedings nor serve the interests of procedural economy.

Request to refer a question to the Enlarged Board of Appeal (Article 112 EPC)

42. Under Article 112(1)(a) EPC, the boards of appeal can refer questions to the Enlarged Board of Appeal either of their own motion or upon request from a party, in order to ensure uniform application of the law or if a point of law of fundamental importance arises, if they consider that a decision is required for the above purposes and if the answer to that question is relevant for ruling on the case in hand.

43. The respondent requested that the board refer a question to the Enlarged Board of Appeal (see section XIII. for the exact formulation).

44. As the board understands it, the question is whether or not a new request filed on appeal which was not decided upon in the decision under appeal but which differs from a request decided upon only on account of the deletion of an entire claim category constitutes an amendment within the meaning of Article 12(4) RPBA and thus whether or not its admittance is subject to the board's discretion.

45. On account of the reasons given above (points 19. to 30.), the board could answer this question itself with certainty.

46. In short, as regards an amendment to a party's case within the meaning of Article 12(4) RPBA, it follows directly from the wording of Article 12(2) and (4) RPBA that any request newly filed on appeal is a request on which the decision under appeal was not based and which therefore has to be regarded as an amendment.

47. As regards the interpretation of what constitutes an amendment to a party's appeal case within the meaning of Article 13 RPBA, the initially diverging views expressed in the case law of the boards of appeal with respect to Article 13 RPBA 2020 appear to have converged towards a common approach. In any case, this issue is not relevant to the case in hand since the circumstances of this case do not satisfy the conditions for deeming claim category deletions not to be an amendment within the meaning of Article 13 RPBA. As set out above, in the case in hand, deleting the product claims in auxiliary request 1 would require novelty and inventive step to be re-assessed and thus would change the legal and factual framework of the appeal.

48. Moreover, the question of whether or not exceptional circumstances within the meaning of Article 13(2) RPBA could be of a legal nature is irrelevant when applying Article 12(4) RPBA. As set out above, considerations in the case law as to whether or not deleting claims present in a previously filed set of claims altered the factual and legal framework of the case or the subject of the discussions or entailed re-evaluating the matters at issue fall under the criteria of

Article 12(4) RPBA. Ultimately, these criteria do not take precedence over the criteria in Article 12(6) RPBA, which are to be applied in parallel and which were also decisive for the board's decision in the case in hand.

49. The board therefore concluded that, in this case, questions did not need to be referred to the Enlarged Board of Appeal under Article 112(1)(a) EPC. The respondent's request was therefore rejected.

Auxiliary requests 2 to 41
Admittance (Article 12(4) and (6) RPBA)

50. Auxiliary requests 2 to 41 were newly filed on appeal. They constitute an amendment to the respondent's case within the meaning of Article 12(4) RPBA (see also section 17 of the reply to the appeal). The admittance of any of these auxiliary requests into the appeal proceedings is therefore at the board's discretion (see also point 30. above).

51. The respondent argued that auxiliary requests 2 to 4 were aimed at addressing novelty objections in relation to various prior-art primers (sections 102, 105 and 107 of the reply to the appeal), while auxiliary requests 5 to 41 were aimed at addressing allegedly new objections raised by the appellant (sections 111, 114, 116 and 119 of the reply to the appeal).

52. The novelty objections addressed in auxiliary requests 2 to 4 had been raised at the outset of the opposition proceedings and therefore could and should have been addressed earlier. As uncontested, none of the auxiliary requests filed during the opposition proceedings contained claims that were limited by only

some – i.e. not all – of the options for defining the first region of claim 10 as granted, as is now the case in auxiliary requests 2 and 4 (sections 33 and 36 of the appellant's submission dated 20 May 2025). It was also uncontested that there was no claim request filed in the opposition proceedings that contained the same independent claims as current auxiliary request 3 (section 37 of the appellant's submission dated 20 May 2025). The board cannot discern any persuasive reasons why claim requests containing these amendments were not filed in the opposition proceedings, or any circumstances of the appeal that would justify filing these requests only on appeal. The respondent did not furnish any either.

53. The allegedly new clarity objections raised by the appellant, addressed in auxiliary requests 5 to 12 (sections 111 and 114 of the reply to the appeal), are irrelevant to the board's decision. Consequently, there was no need to admit and consider auxiliary requests 5 to 11 either.

54. Contrary to the respondent's assertion (see section 115 of the reply to the appeal), the amendment to the definition of the ΔΔG value of the second region in auxiliary requests 13 to 24 was not occasioned by a new argument raised by the appellant concerning the calculation of the ΔΔG value, as assessed above in the context of claim construction (see points 11. to 13.). Consequently, claim requests addressing this objection could and therefore should have been filed earlier. The board cannot discern any persuasive reasons why these claim requests were not filed in the opposition proceedings, or any circumstances of the appeal that would justify filing these requests only on appeal. The respondent did not furnish any either.

55. The allegedly new objection under Article 56 EPC raised by the appellant and addressed in auxiliary requests 25 to 36 (sections 118 to 120 of the reply to the appeal) is irrelevant to the board's decision. Consequently, there was no need to admit and consider auxiliary requests 25 to 36 either.

56. The same considerations on admittance with respect to Article 12(4) and 12(6) RPBA as set out above for auxiliary request 1 apply, *mutatis mutandis*, to the admittance of auxiliary requests 37 to 41, in which the product claims were deleted as in auxiliary request 1 (see points 19. to 41. above). The respondent did not furnish any additional reasons as to why the board should admit these requests.

57. In view of the above considerations, the board decided not to admit and consider auxiliary requests 2 to 41 in the appeal proceedings under Article 12(4) and Article 12(6) RPBA.

Order

For these reasons it is decided that:

1. The request for referral of a question to the Enlarged Board of Appeal is rejected.

2. The decision under appeal is set aside.

3. The patent is revoked.

The Registrar: The Chairwoman:

C. Rodríguez Rodríguez R. Morawetz

Decision electronically authenticated