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Datasheet for the decision of 15 September 2025

Case Number: T 1103/23 - 3.3.08

Application Number: 13764186.6

Publication Number: 2828218

IPC: C12Q1/6876, C12Q1/6869, C12Q1/6806

Language of the proceedings: EN

Title of invention:
Methods of lowering the error rate of massively parallel DNA sequencing using duplex consensus sequencing

Patent Proprietor:
University of Washington through its Center for Commercialization

Opponents:
Withers & Rogers LLP
Margaret Dixon Limited
Lewis Silkin LLP

Headword:
Generating an error-corrected sequence/UNIVERSITY OF WASHINGTON

Relevant legal provisions:
EPC Art. 113(1), 123(2)
RPBA 2020 Art. 12(4), 12(6), 15(3)

Keyword:
Exercise of discretion - correct (no)
Amendments - extension beyond the content of the application as filed (yes)
Late-filed requests - should have been submitted in first-instance proceedings (yes)

Decisions cited:
G 0007/93, G 0002/10, T 1852/13, T 0245/19

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Case Number: T 1103/23 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 September 2025

Appellant: (Patent Proprietor)	University of Washington through its Center for Commercialization 4311 11th Avenue NE Suite 500 Seattle, WA 98105-4608 (US)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 24 May 2023 revoking European patent No. 2828218 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman T. Sommerfeld
Members: R. Morawetz
A. Bacchin

Summary of Facts and Submissions

I. The appeal lodged by the patent proprietor (appellant) lies from the decision of the opposition division revoking European patent No. 2 828 218 B9 (the patent), granted on European patent application No. 13 764 186.6, which was filed as an international application under the PCT and published as WO 2013/142389 A1. The patent is entitled "*Methods of lowering the error rate of massively parallel DNA sequencing using duplex consensus sequencing*".

II. Three oppositions were filed against the patent, which was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.

III. In the decision under appeal, the opposition division considered the set of claims of the main request, which had been filed as main request 3A at the oral proceedings on 22 March 2023, and came to the conclusion that claim 1 contravened Article 123(2) EPC.

IV. With their grounds of appeal, the appellant submitted sets of claims of a main request and auxiliary requests 1 to 19, with the main request corresponding to the main request before the opposition division, and with auxiliary requests 1 to 19 being new.

V. In their replies to the appellant's grounds of appeal, opponent 1 (respondent I), opponent 2 (respondent II) and opponent 3 (respondent III) maintained added matter objections to claim 1 of the main request and disputed

the admissibility of auxiliary requests 1 to 19.

VI. The board scheduled oral proceedings in accordance with the parties' requests and, in a communication pursuant to Article 15(1) RPBA, expressed the preliminary opinion that in admitting the main request, the opposition division had exceeded the proper limits of its discretion; claim 1 of the main request contravened Article 123(2) EPC and auxiliary requests 1 to 19 should have been filed during opposition proceedings.

VII. None of the parties submitted a substantive reply to the board's communication. Respondent II, respondent III and the appellant informed the board by letters received 14 April 2025, 22 April 2025 and 15 May 2025, respectively, that they would not attend the oral proceedings.

VIII. The board cancelled the oral proceedings.

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

X. The parties' requests relevant to the present decision are as follows.

The appellant requests that:

- the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution based on the set of claims of the main request or, alternatively, that the case be remitted to the opposition division based on the set of claims of one of auxiliary requests 1 to 19

- the decision of the opposition division to admit the main request not be overturned by the board

- auxiliary requests 1 to 19 be admitted into the proceedings.

XI. The respondents request that the appeal be dismissed and that auxiliary requests 1 to 19 not be admitted into the proceedings.

In addition, respondent I requests that the main request not be admitted into the appeal proceedings and that oral proceedings be held if the patent is not revoked based on the written submissions alone.

Reasons for the Decision

Decision taken in written proceedings

1. The appellant and respondents II and III stated that they would not attend oral proceedings (see section VII. above).

2. When oral proceedings are scheduled at the request of the parties, as in the case at hand, and a party subsequently declares that it will not be appearing at the hearing (in this case, the appellant and respondents II and III), such a declaration results in the request for oral proceedings becoming ineffective, and the board may dispense with oral proceedings if no other reason makes it necessary or desirable to hold them (see also T 245/19, Reasons 1 and Case Law of the Boards of Appeal of the European Patent Office, 11th edn. 2025 (Case Law), III.C.5.3.2 b)).

3. Since in the current case there is no such reason to hold oral proceedings, the oral proceedings were cancelled, and this decision is taken in written proceedings, based on the minutes of the oral proceedings before the opposition division (minutes); the decision under appeal; the parties' submissions, arguments and requests on appeal; and the board's communication under Article 15(1) RPBA in accordance with Article 12(2) and (8) RPBA and Article 113(1) EPC.

4. Dismissal of the appellant's appeal (see below) complies with the main request of respondent I.

Main request
Admittance and consideration

5. The main request was filed as main request 3A during the oral proceedings before the opposition division. The opposition division admitted the request into the proceedings, and the decision under appeal is based on it.

6. Although on account of Article 12(2) RPBA main request 3A automatically forms part of the appeal proceedings, the board considers it necessary to make the following observations.

7. It is established case law of the boards that on appeal against a decision taken by an opposition division in exercise of its discretion, it is not for the board to review all the facts and circumstances of the case as if it were in that division's place and decide whether or not it would have exercised discretion in the same way. A board may overrule the way in which a first-instance department exercised its discretion if it comes to the conclusion either that the first-instance

department did not exercise its discretion in accordance with the right principles or that it exercised its discretion in an unreasonable way and thus exceeded the proper limits of its discretion (Case Law, V.A.3.4.1 b) and G 7/93, OJ EPO 1994, 775, Reasons 2.6).

8. In accordance with the Guidelines in force at the time of filing of the relevant request, which in this case is also the time of the opposition division's decision (version in force in March 2023), the relevant criterion for deciding on the admissibility of late-filed amendments in opposition proceedings was that "*if these amendments are not clearly allowable (see H-II, 2.7.1), they will not be admitted*" (E-VI, 2.2.3).

9. In Guidelines H-II, 2.7.1, the concept of "*clear allowability*" is further explained as follows: "*late-filed claims will only be admitted into the proceedings if they are clearly allowable. This means that it must be immediately apparent [...] that the amendments successfully overcome the objections without giving rise to new ones (prima facie assessment)*". The Guidelines reflect the established case law of the boards on the criterion for admittance of late-filed requests to be applied in opposition proceedings (Case Law, IV.C.5.1.7 b)).

10. For the reasons set out below, the board agrees with respondent I that the opposition division did not correctly apply the criterion of "*clear allowability*" in exercising its discretion.

11. During oral proceedings, following the rejection of main request 2 because of added matter, the chair of the opposition division pointed out that the

combination of features giving rise to the effect recited in step b) of claim 1 of main request 2, such as the arrangement of primers indicated in paragraph [0023] of the application as filed, had to be present in claim 1 to meet the requirements of Article 123(2) EPC (minutes, page 8, second paragraph).

12. The appellant then filed main request 3A, which did not specify the arrangement of primers in claim 1. Respondent II pointed to further features which were missing from claim 1 and submitted that this request was therefore not *prima facie* compliant with Article 123(2) EPC.

13. However, instead of considering whether it was immediately apparent that the amendments to claim 1 in main request 3A successfully overcame the added matter objection to claim 1, the chair of the opposition division "*noted that the deficiencies under Art. 84 EPC and Art. 123(2) EPC would have to be striking for the requirement of prima facie compliance of a request not to be fulfilled*" (minutes, page 9, third paragraph).

14. In the board's view, this indicates that the opposition division misconstrued the criterion of "*clear allowability*" and consequently applied it incorrectly, interpreting it as "*clear non-allowability*". Indeed, a detailed discussion on the merits of the issue of added subject-matter followed, and the opposition division concluded that main request 3A contravened Article 123(2) EPC because at least four features which according to the application as filed were inextricably linked to the features added in claim 1 had been omitted from claim 1 of main request 3A (point 23. below). This confirms that the opposition division applied wrong principles when admitting

main request 3A.

15. Finally, the opposition division's reasoning for admittance set out in the decision under appeal, i.e. that the main request was "*a bona fide attempt by P to overcome deficiencies under Article 123(2) EPC*" (decision under appeal, Reasons 20.2) further indicates that the opposition division misinterpreted the criterion of "*clear allowability*". In fact, "*a bona fide attempt to overcome deficiencies*", while recalling the general admissibility requirement of Rule 80 EPC, falls short of the stricter requirement of "*clear allowability*" and is irrelevant to the exercise of discretion in admitting late-filed amendments.

16. The board concludes from the above observations that in admitting the main request, the opposition division exceeded the proper limits of its discretion.

17. With respect to respondent I's request that the main request not be admitted into the appeal proceedings, the board observes that the main request forms part of the appeal proceedings because the opposition division admitted it into the proceedings and the impugned decision is based on this request (Article 12(1)(a) and (2) RPBA). The boards do not have the power to retroactively disregard on appeal submissions admitted by opposition divisions in the exercise of their discretion (Case Law, V.A.3.4.3).

18. The board therefore reviewed the opposition division's decision on the merits (Article 12(2) RPBA).

Added subject-matter (Article 100(c) in conjunction with Article 123(2) EPC) - claim 1

19. Reference is made below to the page and line numbering of the A1 publication (section I. above), referred to as the application as filed.

20. The standard for assessing compliance with the requirements of Article 123(2) EPC is the standard set out in decision G 2/10 (OJ EPO 2012, 376, Reasons 4.3), also known as the gold standard. Amendments are only permitted 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 the application as filed. 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 (ibid., Reasons 4.7; see also point 30. below). After the amendment, the skilled person may not be presented with new technical information (ibid., Reasons 4.5.1).

21. According to the appellant, claim 1 of the main request is based on claim 15 as filed. Claim 1 reads as follows (amendments as compared to claim 15 as filed are indicated by underlining and strikethrough; for ease of reference, the individual steps of the method of claim 1 have been labelled a) through h)):

"A method of <u>generating an error-corrected sequence</u> ~~obtaining the sequence~~ of a double-stranded target nucleic acid <u>molecule</u> comprising
a) <u>individually tagging each of the two strands of the double-stranded target nucleic acid molecule by</u> ligating <u>both strands of the</u>~~a~~ double-stranded target

nucleic acid molecule to at least one single molecule identifier (SMI) adaptor molecule comprising an SMI sequence to form a double-stranded SMI-target nucleic acid complex~~;~~, wherein the SMI sequence comprises at least one degenerate or semi-degenerate nucleic acid sequence, such that the SMI-target nucleic acid complex comprises a unique identifier;
b) independently amplifying each strand of the ~~double-stranded~~ SMI-target nucleic acid complex, resulting in each strand generating a distinct yet related~~a~~ set of amplified SMI-target nucleic acid products; and
c) sequencing the amplified SMI-target nucleic acid products comprising the unique identifier;
d) comparing the sequences of the amplified SMI-target nucleic acid products obtained from one strand of the double-stranded target nucleic acid with the sequences of the amplified SMI-target nucleic acid products obtained from the other strand of the double-stranded target nucleic acid,
e) such that a mutation only occurring at a particular position in one or more sequences from one of the strands is identified as an error introduced during amplification or sequencing
f) wherein the SMI sequence is a double-stranded complementary SMI sequence and
g) wherein the double-stranded SMI-target nucleic acid complex comprises an SMI adaptor molecule at each end and the SMI adaptor molecules are each a Y-shape;
h) and wherein each SMI adaptor molecule includes at least two PCR primer or flow cell binding sites."

22. Steps a) to e) were present in claim 1 as granted, while steps f) to h) are post-grant amendments.

Step b) of claim 1

23. The opposition division noted that claim 1 was restricted to the context of Y-shaped adaptors added to each end of the target nucleic acid (see feature g) of claim 1). It held that paragraph [0023] of the application as filed was the sole basis for the features of step b) and that in the application as filed the feature of independently amplifying each strand of the SMI (single molecule identifier)-target nucleic acid complex was inextricably linked to the use of Y-shaped adaptors being characterised by the following additional features: having two distinct PCR primer binding sites (FC1, FC2); the presence of two different SMI sequences and the use of PCR amplification. In addition, the opposition division was of the view that not defining the location of the primer sites and the primers used for independently amplifying the two target strands represented an unallowable generalisation.

24. The appellant contested this finding of the decision under appeal. The appellant's main argument was that paragraph [0080] of the application as filed provided a basis for the feature "*independently amplifying*" and the other feature in step b) of claim 1, which describes the amplification as producing "*distinct yet related*" products. They argued that although these features were not explicitly mentioned in paragraph [0080], the comparison of the amplicons as taught in paragraph [0080] was a direct and unambiguous disclosure of both these features. Therefore, the other features disclosed in paragraph [0023] of the application as filed did not need to be mentioned in claim 1 to avoid an impermissible generalisation.

25. The question to be addressed is therefore whether the teaching in paragraph [0023] of the application as filed can be generalised on the basis of the teaching in paragraph [0080] of the application as filed.

26. Paragraph [0080] of the application as filed states that "[l]*imitations related to sequencing single stranded DNA (e.g., sequencing errors) may therefore be overcome using the methods described herein. This is accomplished by individually tagging and sequencing each of the two strands of a double-stranded (or duplex) target nucleic acid molecule and comparing the individual tagged amplicons derived from one half of a double-stranded complex with those of the other half of the same molecule. Duplex Consensus Sequencing (DCS), significantly lowers the error rate of sequencing*".

27. Thus, paragraph [0080] of the application as filed discloses that amplicons derived from one half of a double-stranded complex can be compared with those of the other half of the same molecule because the two strands are individually tagged. However, paragraph [0080] does not provide any details about the amplified products and is silent as to what other features (structural, functional, method steps or a combination of these) might be required to allow the individually tagged amplicons derived from one half of a double-stranded complex to be compared with those of the other half of the same molecule.

"*independently amplified*"

28. The board agrees with the appellant that in claim 1, the expression "*independently amplifying*" means amplifying the strands in the complex independent of each other, i.e. separately. The board also agrees with

the appellant that paragraph [0080] of the application as filed implicitly discloses an amplification step, as evidenced by the reference to "*amplicons*". However, for the reasons set out below, the board disagrees with the appellant's argument that paragraph [0080] implicitly discloses the feature "*independently amplifying*".

29. The appellant's argument hinges on the assertion that according to paragraph [0080] of the application as filed, amplifying has to result in the ability to compare the amplicons from one strand with amplicons from the other strand and has therefore to provide different sets of amplicons - one from the top strand and one from the bottom strand - and that "[t]*o result in different groups of amplicons, the amplification must have been separate or independent from each other*" (grounds of appeal, page 10).

30. It is established case law of the boards that subject-matter implicitly disclosed to the skilled person, using common general knowledge, in the application as filed as a whole relates solely to matter which is not explicitly mentioned but is a clear and unambiguous consequence of what is explicitly mentioned (Case Law, II.E.1.3.3). An alleged disclosure can only be considered "*implicit*" if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject-matter disclosed.

31. According to paragraph [0080] of the application as filed, the amplicons derived from one strand can be compared with amplicons from another strand because the strands are individually tagged, irrespective of how the amplicons are generated (point 26. above). Furthermore, as correctly noted by respondent II, the

application as filed also discloses amplification as part of a hairpin structure. Amplification as part of a hairpin structure allows comparison of the strands, although it does not involve independent amplification of the strands (paragraphs [0023] and [0034] to [0038] of the application as filed).

32. Thus, it is not a clear and unambiguous consequence of what is explicitly mentioned in paragraph [0080] of the application as filed that the amplicons are "*independently amplified*".

"distinct yet related" products

33. The appellant's argument on the implicit disclosure of "*distinct yet related*" products in paragraph [0080] of the application as filed is based on the assertion that the skilled person would ask the question "*what else does paragraph [0080] tell us about the amplification?*" (grounds of appeal, page 10) and would then, according to the appellant, consider that "[i]*t tells us that the amplification also results in amplicons that can be compared within the same molecule.*
For this comparison, the separate products from the top strand and from the bottom strand produced by amplification have to be different. Otherwise, they could not be distinguished to allow the comparison between them.
For this comparison, the amplicons from the top strand also have to share a similarity with the amplicons on the bottom strand so that they all can be traced back to the same molecule" (ibid.). The appellant also relies on Figure 2, which allegedly shows the comparison disclosed in paragraph [0080] of the

application as filed (grounds of appeal, page 11).

34. In agreement with respondent II, the board considers that the appellant's argument (point 33. above) requires that the skilled person think about the comparison and work out what features of what elements (the tags, adaptors or amplicons, or the physical arrangement of the process) might be required to allow the comparison to occur. It is, however, well established in the case law of the boards that the results of the skilled person's thoughts and reflection do not constitute matter which is a clear and unambiguous consequence of what is explicitly mentioned (Case Law, II.E.1.3.4 b)).

35. In addition, as also correctly observed by respondent II, paragraph [0080] of the application as filed provides a general discussion of the methods described in more detail elsewhere in the application, as evidenced by the reference to "*using the methods described herein*". The board therefore agrees with respondent II that the skilled person would look to these methods described elsewhere in the application as filed for further details on the amplified products rather than apply thought and reflection to the question of what other features - besides individually tagging the two strands - might be required to allow the comparison of the amplicons to occur.

36. In the board's view, the skilled person reading paragraph [0080] of the application as filed would turn to those parts of the application providing information on DCS (see "*Duplex Consensus Sequencing (DCS), significantly lowers the error rate of sequencing*") for further details. DCS is illustrated in Figure 1 of the

application as filed and described in paragraph [0098] of the application as filed.

37. Paragraph [0098] teaches that "[t]*o overcome limitations in the sensitivity of variant detection by single stranded next-generation DNA sequencing, an alternative approach to library preparation and analysis was designed, which is known herein as Duplex Consensus Sequencing (DCS) (Figure 1). The DCS method described herein involves tagging both strands of duplex DNA with a random, yet complementary double-stranded nucleotide sequence, which is known herein as a double-stranded single molecule identifier (SMI) sequence. The SMI sequences (in this case, double stranded SMI sequences) are incorporated into the SMI adaptor molecules by introducing a single-stranded randomized nucleotide sequence into one adapter strand and the extending the opposite strand with a DNA polymerase to yield a complementary, double-stranded SMI sequence (Figure 2). The individually tagged strands are then PCR amplified. Every duplicate that arises from a single strand of DNA will have the same SMI, and thus each strand in a DNA duplex pair generates a distinct, yet related population of PCR duplicates after amplification owing to the complementary nature of the SMIs on the two strands of the duplex*".

38. As noted by respondent I, the application as filed thus teaches that the generation of the distinct yet related population of PCR duplicates is due to (see "*owing to*") the complementary nature of the SMIs on the two strands of the duplex DNA.

39. Finally, the board notes that Figure 2 depicted on page 11 of the appellant's grounds of appeal is not

part of the application as filed. Contrary to the appellant's submission, Figure 2 also does not show the comparison disclosed in paragraph [0080] of the application as filed. Instead, it contains information that cannot be derived directly and unambiguously from paragraph [0080] of the application as filed. For example, paragraph [0080] is silent about the generation of fragments and adaptors with unique molecular tags with asymmetry or their addition to fragments (point 26. above), while these features are part of the method shown in Figure 2.

40. The products being "*distinct yet related*" is therefore not a clear and unambiguous consequence of what is explicitly mentioned in paragraph [0080] of the application as filed.

41. The board concludes from the above considerations that the teaching in paragraph [0023] of the application as filed cannot be generalised based on the disclosure in paragraph [0080] of the application as filed.

42. As a separate line of argument, the appellant submitted that claim 1 is not an impermissible generalisation from paragraphs [0023] and [0098] of the application as filed.

43. For the reasons set out below, this is not persuasive either.

44. As regards the teaching of paragraph [0098], reference is made to points 37. and 38. above. Paragraph [0023] of the application as filed reads "[t]*he SMI adaptor molecule may form a 'Y-shape' or a 'hairpin shape.' In some embodiments, the SMI adaptor molecule is a 'Y-shaped' adaptor, which allows both strands to be*

independently amplified by a PCR method prior to sequencing because both the top and bottom strands have binding sites for PCR primers FC1 and FC2 as shown in the examples below. A schematic of a Y-shaped SMI adaptor molecule is also shown in Figure 2. A Y-shaped SMI adaptor requires successful amplification and recovery of both strands of the SMI adaptor molecule".

Placement and type of PCR primers

45. Paragraph [0023] of the application as filed explicitly attributes the ability to be independently amplified to the use of a Y-shaped adaptor and to the presence of binding sites for the PCR primers FC1 and FC2 in both the top and bottom strands. As noted by the opposition division, this is also disclosed in paragraph [0031] of the application as filed which refers to a forward PCR primer binding site (FC1) and a reverse PCR primer binding site (FC2).

46. Claim 1 stipulates that the double-stranded SMI-target nucleic acid complex comprises a Y-shaped SMI adaptor molecule at each end and that each SMI adaptor molecule includes at least two PCR primer or flow cell binding sites (features (g) and (h)). These PCR primer or flow cell binding sites are not further defined regarding their structure or location within the Y-shaped SMI adaptor molecule.

47. The appellant argued that the feature that the adaptors have different binding sites for the PCR primers FC1 and FC2 is already present in claim 1 as a result of the Y-arms of the SMI adaptor molecule (feature g) of claim 1). It submitted that the adaptor arms must have different sequences because otherwise the adaptor would

not be Y-shaped.

48. The board disagrees. Claim 1 does not require the PCR primer or flow cell binding sites to be present in the arms of the Y-shaped SMI adaptor molecule. Contrary to the submission by the appellant, the feature that the adaptors have different binding sites is therefore not present in claim 1 as a result of the Y-arms.

49. In addition, the board agrees with respondent II that the disclosure of the application as filed requires that the SMI adaptor molecules each comprise binding sites for forward PCR primer FC1 and reverse PCR primer FC2. As a consequence, once the two adaptors are added, the application teaches that both the top and bottom strands to be amplified comprise binding sites for the PCR primers FC1 and FC2. This is neither stated nor unambiguously implied by claim 1.

50. Although the appellant acknowledged that claim 1 does not explicitly state that the PCR primer binding sites are at the ends of the adaptors, it argued that the feature of the primer binding sites being in the arms is already part of the claim because "*the claim requires amplifying the SMI-target nucleic acid complex, the Y arms being part of that complex. Furthermore, this is done to generate a distinct yet related set of amplicons. This distinctiveness is as a result of the Y-arms*" (grounds of appeal, page 13).

51. The board understands the appellant's argument to be that the claim requires the complex to be amplified in its entirety, including the Y-arms, which can only be the case if the primer binds to the Y-arms. The board agrees with respondent II that this does not in fact seem to be a requirement of the claim, which only

requires that the amplification results in a "*set of amplified SMI-target nucleic acid products*". Nor is it apparent from the claim that the "*distinct yet related*" set of amplicons arises from the Y-arms.

52. Finally, the appellant submitted that paragraph [0023] of the application as filed uses FC1 and FC2 for amplification and argued that these are flow cell binding sites. However, paragraph [0023] expressly refers to binding sites for the PCR primers FC1 and FC2.

Two different SMI sequences

53. It is undisputed that paragraph [0098] of the application as filed explicitly attributes the ability to generate a *"distinct, yet related"* set of amplicons to the complementary nature of the SMIs on the two strands of the duplex, while claim 1 is silent about the structure of the SMI sequences.

54. As regards the appellant's argument that paragraph [0098] of the application as filed was not the sole basis for *"distinct yet related"* and that paragraph [0080] of the application as filed, which was not linked with specific structures, provided a general basis for the feature of producing *"distinct yet related"* products (amplicons), the board refers to points 33. to 40. above. This argument thus fails.

55. The board is also not persuaded by appellant's further argument that paragraph [0098] of the application as filed was presented as an overview and that although the method was explained only on the basis of the structures contained there, the skilled person would understand that the Y adaptors described there merely

served as an aid to explaining how the method worked in general.

56. As noted by respondent II, paragraph [0098] of the application as filed refers to Figure 1 and describes the effects of the structural features depicted in that figure (point 37. above). The board considers that there is no reason for a skilled person to understand that these effects could be separated from the structural features that cause them.

PCR amplification

57. The appellant did not contest that paragraph [0023] of the application as filed discloses independent amplification by a PCR method. Instead, it referred to the three-point test and argued that the omission of "*PCR*" from claim 1 did not add matter.

58. The board is not persuaded by this argument. The test for compliance with Article 123(2) EPC has been set out in point 20. and point 30. above, and the so-called three-point or essentiality test cannot take the place of the standard set out in G 2/10. Furthermore, it is well established in the case law of the boards that the essentiality test is no longer considered appropriate (see Case Law, II.E.1.4.4 c) and, e.g. T 1852/13, Reasons 2.2.3).

59. The board concludes from the above that claim 1 of the main request contravenes Article 123(2) EPC and therefore sees no reason to set the decision under appeal aside.

Auxiliary requests 1 to 19
Admittance and consideration

60. In view of the primary purpose of the appeal proceedings - to review the decision under appeal in a judicial manner - a party's appeal case must be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based (Article 12(2) RPBA).

61. Under Article 12(4) RPBA, any part of a party's appeal case which does not meet the requirements in Article 12(2) RPBA is to be regarded as an amendment unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the decision under appeal.

62. Auxiliary requests 1 to 19 were first submitted on appeal.

63. Claim 1 of each of auxiliary requests 1 to 9 is based on claim 1 of the main request, to which the following amendments (indicated by underlining and strikethrough) have been made.

In claim 1 of auxiliary request 1, step h) is amended to read "*and wherein each SMI adaptor molecule includes at least two different PCR primer or flow cell binding sites*".

In claim 1 of auxiliary request 2, step h) is amended to read "~~*and*~~ *wherein each SMI adaptor molecule includes at least two different PCR primer or flow cell binding sites and wherein the different PCR primer or flow cell binding sites flank the SMI sequence*".

In claim 1 of auxiliary request 3, step h) is amended to read "*~~and~~ wherein each SMI adaptor molecule includes at least two different PCR primer or flow cell binding sites and wherein the different PCR primer or flow cell binding sites are located at the end of the Y arms*".

In claim 1 of auxiliary request 4, step h) is amended to read "*~~and~~ wherein each SMI adaptor molecule includes at least two different PCR primer or flow cell binding sites which allows both strands to be independently amplified by providing both the top and the bottom strands with PCR primer or flow cell binding sites*".

In claim 1 of auxiliary request 5, step g) is amended to read "*wherein the SMI sequence is a double-stranded complementary SMI sequence and wherein the double-stranded SMI-target nucleic acid molecule complex comprises an SMI adaptor molecule at each end and the SMI adaptor molecules are each a Y-shape and each SMI sequence is distinct from the other SMI sequence in the SMI-target nucleic acid complex;*".

In claim 1 of auxiliary request 6, step b) is amended to read "*independently amplifying by PCR each strand of the SMI-target nucleic acid complex, resulting in each strand generating a distinct yet related set of amplified SMI-target nucleic acid products;*".

In claim 1 of auxiliary request 7, step h) is amended to read "*and wherein each SMI adaptor molecule includes at least two PCR primer ~~or flow cell~~ binding sites*".

Claim 1 of auxiliary request 8 combines the amendments made to steps b), g) and h) in auxiliary requests 2 and 4 to 7.

Claim 1 of auxiliary request 9 combines the amendments made to steps b), g) and h) in auxiliary requests 3 and 4 to 7.

64. Claim 1 of auxiliary requests 10 to 19 is based on claim 1 of the main request and auxiliary requests 1 to 9, respectively, in which step a) has been amended to read "*wherein the unique identifier is the SMI sequence from the at least one SMI adaptor molecule; or wherein the double-stranded target nucleic acid molecule is a sheared double-stranded DNA fragment and the unique identifier is a combination of the SMI sequence from the at least one SMI adaptor molecule and sheared ends of the sheared double-stranded DNA fragment*".

65. The appellant has not demonstrated that any of these requests was admissibly raised and maintained in the proceedings leading to the decision under appeal (Article 12(4) RPBA).

66. With respect to the appellant's argument that claim 1 of auxiliary request 1 is a combination of "*claims 1 and 9 of AR14 filed by R116 deadline*" (grounds of appeal, page 18, table) and that claim 1 of auxiliary request 6 is a combination of "*claims 1, 8 and 9 of AR14*" (ibid.), the board agrees with the respondents that this is irrelevant because the requests as a whole are new.

67. Finally, with respect to auxiliary requests 10 to 19, the board agrees with respondent II that the appellant's argument that the "[a]*dditional amendment to define unique identifier submitted as AR22 on 21 February 2023*" (grounds of appeal, page 19, table) as compared to auxiliary requests 1 to 9 was submitted during first-instance proceedings does not help because

the requests as a whole were not present in the first-instance proceedings.

68. Auxiliary requests 1 to 19 therefore constitute an amendment of the appellant's case within the meaning of Article 12(4) RPBA, which can only be admitted into the proceedings at the discretion of the board.

69. Pursuant to Article 12(6) RPBA, the board must not admit requests, facts, objections or evidence which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

70. By way of justification for filing new auxiliary requests on appeal, the appellant submitted that "[i]*n the preliminary opinion from the OD, the particular feature of 'independently amplified' was read in the context of the step as a whole and was therefore not restricted to paragraph 23 for basis. The new requests are responsive to the change in the opinion of the OD during oral proceedings to paragraph 23 only being the basis for this phrase*" (emphasis in the original, appellant's grounds of appeal, paragraph bridging pages 17 and 18).

71. The respondents requested that auxiliary requests 1 to 19 not be admitted as they could and should have been filed in opposition proceedings or because they are complex, lack procedural economy and are unsuitable for addressing the issues which lead to the decision under appeal.

72. The question thus arises whether in the circumstances of the current case, the appellant had a reason - and

an opportunity - to submit auxiliary requests 1 to 19 in the opposition proceedings.

73. The patent was revoked because the opposition division concluded that step b) of claim 1 of the main request added subject-matter (point 23. above).

74. The objection that the feature "*independently amplifying each strand of the SMI-target nucleic acid complex*" in step b) of claim 1 represents an unallowable generalisation of the disclosure in paragraph [0023] of the application as filed was raised at the outset of the opposition proceedings by all respondents. In addition, respondents I and II noted that only paragraph [0098] of the application as filed taught a "*distinct, yet related*" set of products, but only in the context of other features not present in claim 1 as granted, including the method of DCS as outlined in Figure 1 of the application as filed and a complementary, random double-stranded SIM.

75. In reply to the notices of opposition, the appellant argued that a basis for step b) of claim 1 was found in the application as filed in paragraph [0098], following on from the explanation given in paragraph [0080], but it did not submit a single fall-back position addressing this or any other added subject-matter objection.

76. In its communication issued in preparation for the oral proceedings, the opposition division provisionally considered that the features of "*independently amplifying each strand of the double-stranded SMI-target nucleic acid complex*" and "*resulting in each strand generating a distinct yet related set of amplified SMI-target nucleic acid products*" had "*to be*

considered in context, as amplified strands are a result of the amplification step and cannot be separated therefrom" (opposition division's communication, item 10.6). However, contrary to the appellant's assertion (point 70. above), the opposition division did not consider that these features were not restricted to paragraph [0023] of the application for a basis (ibid.). Instead, the opposition division held that these features had no basis in the application as filed, even taking into account paragraphs [0080] and [0098] as cited by the appellant (ibid.). The opposition division also noted that paragraph [0098] disclosed several features that were not reflected in the wording of claim 1 of the main request then on file (ibid.).

77. In response to the preliminary opinion of the opposition division, and within the time limit under Rule 116(2) EPC, the appellant submitted auxiliary requests 1 to 21, with auxiliary request 1 meant to address the objection in item 10.6 of the preliminary opinion.

78. One month prior to the oral proceedings, the appellant submitted auxiliary requests 22 to 39, which addressed a different added subject-matter objection.

79. During the oral proceedings, the appellant repeatedly submitted amended versions of its main request, the final version of which, main request 3A, forms the basis of the decision under appeal and contains, in addition to step (b), steps (g) and (h) (see point 21. above).

80. The opposition division found that the only basis for step (b) of claim 1 of the main request was provided by

paragraph [0023] of the application and that the omission of several features disclosed in the context of two Y-shaped SMI adaptor molecules ligated to both ends of the double-stranded target nucleic acid molecule resulted in an impermissible generalisation.

81. Contrary to the appellant's submission, the board does not consider that the opposition division changed its opinion at the oral proceedings compared with the opinion issued in preparation for them. The opposition division explained in its preliminary opinion that the feature "*independently amplifying each strand of the SMI-target nucleic acid complex*" in step b) of claim 1 had no basis in the application as filed (point 76. above). The reasons given in the decision under appeal are a direct consequence of the amendment to claim 1 of the main request including Y-shaped SMI adaptor molecules but not the other features disclosed along with them in the application as filed. Accordingly, the appellant's justification for submitting auxiliary requests 1 to 19 only on appeal is not found persuasive.

82. The board concludes from the above that the amendments made in auxiliary requests 1 to 19 aim to address an objection raised by the respondents at the outset of the opposition proceedings. This objection was found justified by the opposition division as early as in the preliminary opinion issued in preparation for the oral proceedings (opposition division's communication, item 10.6).

83. It is well established in the case law of the boards 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 (Case Law, V.A.4.3.7 a). Auxiliary requests 1 to 19 should therefore have been filed during opposition proceedings (Article 12(6) RPBA). It is also not apparent to the board that the appellant was in any way prevented from filing requests corresponding to auxiliary requests 1 to 19 during the opposition proceedings.

84. The board therefore exercises its discretion under Article 12(6) RPBA to the effect that auxiliary requests 1 to 19 are not admitted and considered in the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

L. Stridde T. Sommerfeld

Decision electronically authenticated