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Datasheet for the decision of 15 June 2021

Case Number: T 1221/19 - 3.3.08

07008271.4 Application Number:

Publication Number: 1808496

C12Q1/6837, B01J19/00 IPC:

Language of the proceedings: EN

Title of invention:

Methods of sequencing polynucleotide arrays, and preparation methods therefor

Patent Proprietor:

Illumina Cambridge Limited

Opponent:

Kilger, Christian

Headword:

Polynucleotide arrays/ILLUMINA

Relevant legal provisions:

EPC Art. 84, 114(1), 123(3)

Keyword:

Adapted description - added matter (no); clarity (yes);

Decisions cited:

G 0009/91, G 0003/14, T 0500/01, T 0061/03, T 0142/05, T 2227/14

Catchword:



Beschwerdekammern Boards of Appeal

Chambres de recours

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Case Number: T 1221/19 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 June 2021

Appellant: Kilger, Christian Wachtelstr. 4 14195 Berlin (DE)

Representative: CH Kilger Anwaltspartnerschaft mbB

Fasanenstraße 29 10719 Berlin (DE)

Respondent: Illumina Cambridge Limited

(Patent Proprietor) 19 Granta Park Great Abington

Cambridge CB21 6DF (GB)

Representative: Stratagem IPM Limited

Meridian Court Comberton Road

Toft, Cambridge CB23 2RY (GB)

Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on

1 April 2019 concerning maintenance of the European Patent No. 1808496 in amended form.

Composition of the Board:

Chairman B. Stolz
Members: P. Julià
D. Rogers

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Summary of Facts and Submissions

- I. European patent no. 1 808 496 is based on European patent application no. 07 008 271.4, a divisional application of the European patent application no. 02 712 025.2 (EP 1 356 119), originally filed under the PCT and published as WO 02/061126. The patent was opposed on the grounds set forth in Articles 100(a), (b) and (c) EPC and maintained by the opposition division in amended form on the basis of an auxiliary request 2.
- II. A first appeal concerning the patent in suit was lodged by the opponent and, in the decision T 2227/14 of 31 January 2018, this board in the same composition set aside the decision of the opposition division and remitted the case to the opposition division with the order to maintain the patent with the main request filed on 31 January 2018 and a description to be adapted thereto.
- III. Subsequent to this remittal, in a communication pursuant to Article 101(1) EPC and Rules 81(2) and 81(3) EPC, the opposition division invited the patent proprietor to submit a description adapted to the main request and the opponent to comment thereupon. With submissions dated 22 June 2018 and 24 August 2018, the patent proprietor and the opponent filed, respectively, the description adapted to the main request and comments thereupon. As an auxiliary measure, oral proceedings were requested by the opponent.
- IV. Summons to attend oral proceedings were issued by the opposition division and, in reply thereto, both parties filed submissions. After requesting a postponement of

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the oral proceedings that was not granted by the opposition division, the opponent withdrew the request for oral proceedings. The opposition division cancelled the oral proceedings and decided that the description, with an amendment introduced into page 3, met the requirements of the EPC.

- V. The opponent (appellant) lodged a second appeal concerning the patent in suit and, in the statement setting out the grounds of appeal, requested that the decision under appeal be set aside and that the patent be revoked. As an auxiliary measure, oral proceedings were requested. The patent proprietor (respondent) replied thereto and requested to dismiss the appeal and, if oral proceedings were held, an apportionment of costs.
- VI. The parties were summoned by the board to oral proceedings scheduled for 8 October 2021. In a communication pursuant to Article 17 of the Rules of Procedure of the Boards of Appeal (RPBA 2020), the parties were informed of the board's provisional opinion on the issues of the appeal.
- VII. Without making substantive submissions, the respondent requested that the oral proceedings be held by videoconference. If this request was granted, the respondent was ready to withdraw the request for an apportionment of costs.
- VIII. Without making substantive submissions, the appellant withdrew its request for oral proceedings.
- IX. The board cancelled the oral proceedings and informed the parties that it intended to issue a decision in line with the provisional opinion as summarised in the

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conclusions set out in the communication pursuant to Article 17 RPBA 2020.

X. In the decision under appeal, the pages of the description for the maintenance of the patent as amended were indicated to be:

pages 2, 4, 5, 7, 8 of the patent specification

page 6 filed during the oral proceedings on 24 September 2014, and

page 3 filed on 22 June 2018.

- XI. The sole objection raised by the appellant in the statement of grounds of appeal concerned an extension of the scope of protection conferred by the patent (Article 123(3) EPC). The objection arose from the reference on page 6 of the description of the patent as amended to "US-A-56<u>3</u>4413" instead of "US-A-56<u>5</u>4413" as in the granted patent.
- XII. The arguments of the appellant insofar as relevant to the present decision may be summarised as follows:

According to the case law, the patent, being a legal document, was its own dictionary and defined technical terms and determined how a skilled person had to interpret a specific term when used in the description or the claims (T 500/01 of 12 November 2003, point 6 of the Reasons, and T 61/03 of 12 April 2005, point 4.2 of the Reasons). On page 6 of the granted patent, it was stated that, according to one embodiment of the invention, the sequencing referred to in clam 1 was performed as in the patent US-A-56**5**4413. Thus, this reference clearly defined features of claim 1, in

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particular the feature related to "the sequencing is carried out by the **stepwise identification** of fluorescently labelled nucleotides incorporated onto a strand complementary to the single polynucleotides". Such a sequencing and stepwise identification were disclosed in column 16, line 60 to column 17, line 46 of patent US-A-56**5**4413. The reference on page 6 of the description of the granted patent to US-A-56**5**4413 introduced or provided concrete limitations to granted claim 1. These limitations were not provided by the erroneous reference to US-A-56**3**4413 in amended page 6 of the description. Therefore, claim 1 as granted had a narrower scope than claim 1 of the main request with the amended page 6 of the description (T 142/05 of 13 June 2006, headnote and point 4 of the Reasons).

XIII. The arguments of the respondent insofar as relevant to the present decision may be summarised as follows:

Appellant's objection related to amendments of the description made during the opposition procedure which were on file before the filing of the first appeal. The appellant had already had an appeal on the issues raised in the present appeal proceedings. After the first appeal proceedings, a minor amendment to the description was submitted in June 2018 as requested by the opposition division. The amendment on page 3 of the description was not appealed in the present appeal proceedings. Thus, there were no grounds raised in the present appeal proceedings which had not already been addressed in the first appeal proceedings. It was not in the interest of the EPO to allow the appellant to appeal the same issues in perpetuity, and to commence a second appeal on the same issues as a previous appeal. Therefore, the process had to be concluded without

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- requiring the patentee to wait for the conclusion of a second appeal.
- XIV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.
- XV. The respondent (patent proprietor) requested that the appeal be dismissed.

Reasons for the Decision

1. The present decision is based on the same grounds, arguments and evidence on which the board's provisional opinion was based. This opinion was neither questioned by any of the parties, nor did other aspects come up that would require its reconsideration.

The subject of the present appeal

- 2. In view of the respondent's arguments concerning the matter of the present appeal and the request that the process be concluded without requiring the respondent to wait for the conclusion of a second appeal, the board, in the communication pursuant to Article 17 RPBA 2020, drew the parties' attention to the following issues:
- 2.1 Appellant's objection raised under Article 123(3) EPC arises from an amendment made on page 6 of the description. The amended page 6 was filed by the patent proprietor on 24 September 2014. In a (first) decision issued by the opposition division on 24 October 2014, the opposition division considered this objection not to be relevant (cf. page 8, point 11 et seq.). This

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(first) decision was appealed by the opponent (appellant).

- In a communication pursuant to Article 15(1) RPBA 2007 issued on 14 September 2017 during the first appeal proceedings, the board referred to the objection raised under Article 123(3) EPC. The board stated that this objection would become relevant only if the board eventually concluded that any of the requests on file fulfilled the requirements of the EPC and an adapted description would be filed at the proceedings before the board (cf. pages 7 and 8, points 20 and 21, respectively).
- 2.3 In the decision T 2227/14 of 31 January 2018 of the first appeal proceedings, the main request was considered not to contravene Article 123(3) EPC (cf. point 10 of the Reasons) and to fulfil all requirements of the EPC. The board decided to remit the case to the department of first instance for adaptation of the description. No decision was therefore taken on the description then on file and, in particular, on the amendment introduced into page 6 of the description.
- 2.4 Thus, appellant's objection raised under
 Article 123(3) EPC against the amendment introduced
 into page 6 of the description became only relevant
 after remittal to the opposition division.
- 3. In view of these considerations, the respondent's request that the process be concluded without requiring the respondent to wait for the conclusion of a second appeal, cannot be granted.

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The patent as granted and the amendments thereto

- 4. The set of 15 claims as granted contained three independent claims, namely claims 1, 11 and 14, which read as follows:
 - "1. A method of sequencing an array of single polynucleotides wherein the array has a density of from 10^6 to 10^9 single polynucleotides per cm² and a higher density of relatively short molecules, whereby those parts of the single polynucleotides that extend beyond the relatively short molecules can be individually resolved by optical means, wherein the sequencing is carried out by the stepwise identification of fluorescently labelled nucleotides incorporated onto a strand complementary to the single polynucleotides and wherein the identification is achieved by scanning the array using a sequential scanning apparatus which shifts between images." (in bold by the board)
 - "11. A method for the production of an array of polynucleotides which are at a density of 10⁶ to 10⁹ individually resolvable polynucleotides per cm², comprising arraying on the surface of a solid support a mixture of relatively short molecules and relatively long polynucleotides, wherein the relatively short molecules are in excess and wherein the relatively short molecules and the relatively long polynucleotides are arrayed separately, with the relatively short molecules being brought into contact with the solid support first." (in bold by the board)
 - "14. Use of a device comprising a high density array of relatively short molecules and relatively long polynucleotides immobilised on the surface of a solid support, wherein adjacent polynucleotides of the array

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are separated by a distance of at least 10 mm for monitoring the incorporation of nucleoside triphosphates onto a strand complementary to the long polynucleotides, comprising resolving the arrayed polynucleotides by optical means with an imaging device which comprises a sequential scanning apparatus which shifts between images." (in bold by the board)

Claims 2 to 10 as granted were directed to particular embodiments of the method of sequencing according to granted claim 1. Claims 12 and 13 as granted were directed to particular embodiments of the method for production of an array of polynucleotides according to granted claim 11. And claim 15 as granted was directed to a particular embodiment of the use according to granted claim 14, namely for obtaining genetic sequence information.

- 5. The set of 13 claims of the main request underlying the decision T 2227/14 (supra) of the first appeal proceedings contained two independent claims, namely claims 1 and 11, which read as claims 1 and 11 as granted except for the following amendments (in italics):
 - "1. A method of sequencing an array of single polynucleotides wherein ... [as granted claim 1] ... single polynucleotides per cm² and a higher density of greater than 10¹² molecules/cm² of relatively short molecules, whereby ... [as granted claim 1]." (emphasis added by the board)
 - "11. A method for the production of an array of polynucleotides which ... [as granted claim 11] ... wherein the relatively short molecules are at a density

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of greater than 10^{12} molecules/cm² and wherein ... [as granted claim 11]." (emphasis added by the board)

The dependency and subject-matter of claims 2 to 10 and claims 12 and 13 of the main request were identical to those of claims 2 to 10 and claims 12 and 13 as granted.

- 6. The reference to "US-A-56**5**4413" is found in paragraphs [0053] and [0054] of the granted patent.
- 6.1 Paragraph [0053] starts on the last line on page 5 of the granted patent reading "In particular, the arrays may be used in conventional assays which rely on the detection of fluorescent labels", and the sentence continues on page 6 of the granted patent further reading "to obtain information on the array polynucleotides. The arrays are particularly suitable for use in multi-step assays where the loss of synchronisation in the steps was previously regarded as a limitation to the use of arrays. The arrays may be used in conventional techniques for obtaining genetic sequence information. Many of these techniques rely on the stepwise identification of suitably labelled nucleotides, referred to in US-A-5654413 as "single base" sequencing methods". (emphasis by the board)
- Paragraph [0054] on page 6 of the granted patent starts with the sentence reading "In an embodiment of the invention, the sequence of a target polynucleotide is determined in a similar manner to that described in US-A-5654413, by detecting the incorporation of nucleotides into the nascent strand through the detection of a fluorescent label attached to the incorporated nucleotide" (emphasis by the board). After this sentence, the paragraph further describes the

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priming of the target polynucleotide and the extension of the nascent chain in a stepwise manner by polymerase reaction, wherein "[e]ach of the different nucleotides (A, T, G and C) incorporates a unique fluorophore at the 3' position which acts as a blocking group to prevent uncontrolled polymerisation ... The array surface is then cleared of unincorporated nucleotides and each incorporated nucleotide is "read" optically by a charge-coupled device using laser excitation and filters."

- Thus, these paragraphs in the description of the granted patent relate to the method of sequencing an array of single polynucleotides as in granted claim 1 and the use of a device comprising a high density array as in granted claim 14, in particular, in granted claim 15. Since the subject-matter of granted claims 14 and 15 is not present in the main request underlying decision T 2227/14 (supra), these paragraphs relate solely, and if at all, to the method of sequencing of an array of single polynucleotides as in claim 1 of the main request.
- 7. It is undisputed that the patent "US-A-56**5**4413", with the title "Compositions for sorting polynucleotides", relates to the "single base" sequencing methods referred to in paragraph [0053] and further described in paragraph [0054] of the patent as granted.
- 7.1 Contrary thereto, the patent "US-A-56<u>3</u>4413", cited on amended page 6 filed on 24 September 2014 and with the title "Method for thermal oxidation of liquid waste substances w/two-fluid auto-pulsation nozzles", is fully unrelated to, and has nothing to do with, the "single base" sequencing methods referred to in paragraphs [0053] and [0054] of the granted patent.

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7.2 Thus, the reference to the patent "US-A-5634413" is technically meaningless and clearly erroneous. There is a sole reason for introducing this erroneous reference into page 6 of the description, namely to overcome an objection raised under Article 123(2) EPC by the appellant during the opposition proceedings; an objection based on the fact that the patent application as originally filed erroneously cited this patent number instead of the correct number, "US-A-5654413".

Article 123(3) EPC

- 8. Article 123(3) EPC requires the European patent not to be amended in such a way as to extend the protection it confers. According to the established case law, Article 123(3) EPC refers to the totality of protection established by the claims as granted and thus, it is necessary to decide whether or not the totality of the claims before amendment in comparison with the totality of the claims after amendment extends the protection conferred (cf. "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, II.E.2.2, 502).
- 9. Claim 1 of the main request is identical to claim 1 as granted except for the introduction of a feature that further defines the density of the relatively short molecules (supra), i.e. a limiting or restricting feature. Thus, a priori, the scope of protection of claim 1 of the main request appears to be narrower than that of claim 1 as granted.
- 10. However, the appellant referred to the case law and argued that the patent was its own dictionary, defining the technical terms and determining how a skilled person had to interpret a specific term when used in

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the description or the claims (T 500/01 and T 61/03, supra). Therefore, according to the appellant, the reference on page 6 of the description of the granted patent to US-A-5654413 introduced concrete limitations to granted claim 1 that were not provided by the erroneous reference to US-A-5634413 in amended page 6 of the description. Thus, claim 1 as granted had a narrower scope than claim 1 of the main request with the amended page 6 of the description and thus, Article 123(3) EPC was contravened.

- 11. In the board's view, the case law referred to by the appellant relates to the interpretation of ambiguous terms in the claims (cf. "Case Law", supra, II.A.6.3.3, 311). As stated by the appellant, the amendment of the description may sometimes result in a shifting of the interpretation of ambiguous terms or features in the claims and in an extension of their scope of protection (cf. "Case Law", supra, II.E.1.14.4, 497).
- However, in the board's view, there are no ambiguous terms or unclear features in claim 1 of the main request. Neither the term "sequencing" nor the feature "stepwise identification of fluorescently labelled nucleotides incorporated onto a strand complementary to the single polynucleotides" are ambiguous or unclear. They may be broad and unspecific, but not ambiguous or unclear. Thus, it is questionable whether a skilled person would have consulted or drawn on the description for an interpretation of this term in the claims. In the board's view, this is not the case.
- 13. Indeed, it is also established case law that implicit restrictive features which are not suggested by the explicit wording of the claim cannot be read into the claim. There is no reason to use the description to

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interpret an excessively broad claim more narrowly, if it is a question not of understanding concepts, terms or features, but rather of examining an excessively broad request in relation to the state of the art (cf. "Case Law", *supra*, I.C.4.8, 122, and II.A.6.3.4, 312).

- 14. In line therewith, the board considers that, in the present case, there is no need for a skilled person to consult the description for defining or determining the scope of claim 1 as granted and claim 1 of the main request. Moreover, it is worth noting here that the reference on page 6 of the description of the patent as granted states that "[i]n an embodiment of the invention, the sequence of a target polynucleotide is determined in a similar manner to that described in US-A-5654413" (emphasis by the board). The term "similar" is not, and cannot be equated to, the term "identical" and thus, it is even more questionable whether (any and which of) the "concrete limitations" referred to by the appellant in the statement of grounds of appeal formed part of granted claim 1. As stated above, the board considers that none of them formed part of claim 1 as granted.
- 15. The reference in paragraph [0053] states only that the patent US-A-5654413 refers to the "[m]any conventional techniques for obtaining genetic sequence information ... [that] rely on the stepwise identification of suitably labelled nucleotides", as "single base" sequencing methods. All these conventional techniques are encompassed by, and fall within, the scope of protection of claim 1 as granted as well as of claim 1 of the main request, regardless of the name given or referred to them by the patent US-A-5654413.

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16. It immediately follows from these considerations that the reference to the patent US-A-5634413 on amended page 6 of the description, as it is also the case for the reference to the patent US-A-5654413 on page 6 of the granted patent, has no bearing, and no influence, on the definition and determination of the scope of claim 1 and therefore, the amendment introduced into page 6 of the description does not extend in any manner the scope of protection of the claims (Article 123(3) EPC).

Conclusion on Article 123(3) EPC

17. The amendment introduced into page 6 of the description filed during the oral proceedings in opposition on 24 September 2014 does not contravene Article 123(3) EPC.

Article 114(1) EPC - Facts under examination

- 18. According to the decision G 9/91 (OJ EPO 1993, 408; point 19 of the Reasons), in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (e.g. with regard to the provisions of Article 123(2) and (3) EPC).
- 19. In the present case, the amendment introduced on page 6 of the description during the opposition proceedings on 24 September 2014 overcame an objection raised under Article 123(2) EPC by the appellant during the opposition proceedings and thus, its introduction was in accordance with Rule 80 EPC. Moreover, the amendment, as stated above, does not contravene Article 123(3) EPC.

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- In the decision G 3/14 (OJ EPO 2015, A102), the 20. Enlarged Board stated that the requirements of Article 84 EPC are part of the requirements of the European Patent Convention within the meaning of Article 94 EPC that have to be fulfilled on grant, and that Article 94 EPC requires that the application and the invention to which it relates, i.e. the whole content, must be examined for compliance with the requirements of the EPC (G 3/14, supra, points 48, 49 and 54 of the Reasons). In this decision, the Enlarged Board of Appeal stated that in considering whether, for the purpose of Article 101(3) EPC, a patent as amended meets the requirements of the EPC, the claims of the patent may be examined for compliance with Article 84 EPC only when, and then only to the extent that, the amendment introduces non-compliance with Article 84 EPC (Order of the decision) (in italics by the board).
- 21. In line therewith, the board considers that the description of the patent may also be examined for compliance with Article 84 EPC only when, and then only to the extent that, the amendment introduces non-compliance with Article 84 EPC. This is in accordance with both decisions, G 9/91 and G 3/14. Thus, it is for the board to assess whether the amendment introduced on page 6 of the description on 24 September 2014 introduces non-compliance with Article 84 EPC.

Article 84 EPC

22. It is common ground between the parties that the reference to the patent US-A-56<u>3</u>4413 is erroneous and technically meaningless. This was acknowledged also by the examining and the opposition division during the

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examination and the opposition proceedings, respectively. Thus, in the board's view, it would also be immediately evident for, and obvious to, a skilled reader that the disclosure of the patent US-A-5634413 has clearly no bearing on that of the granted patent and, in particular, on the subject-matter of the claims as granted.

- 23. In this sense, the erroneous reference to the patent US-A-56<u>3</u>4413 does not lead to any lack of clarity or ambiguity, because it is so clearly and unambiguously unrelated to the disclosure of the granted patent and the subject-matter of the claims that the skilled reader would immediately ignore and disregard this reference.
- 24. Moreover, in the light of the disclosure of paragraphs [0053] and [0054], the board also considers that, for a skilled person, ignoring or disregarding the reference to the patent US-A-5634413 on page 6 of the description does not result in any lack of clarity or ambiguity of the disclosure of these paragraphs.
- Paragraph [0053] refers to (many) conventional techniques that rely on the stepwise identification of suitable nucleotides, the erroneous reference to the patent US-A-5634413 only names these (many) conventional techniques, namely as "single base" sequencing methods. This name may still be correct in spite of the erroneous reference, and the nature of these (many) conventional techniques and their availability to a skilled person is not changed or altered in any manner by said erroneous reference.
- 24.2 Paragraph [0054] states first that the sequence of a target polynucleotide is determined in a manner which

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is similar to that described in the erroneous reference to the patent US-A-5634413 and, immediately thereafter, several steps of the sequencing method are described. Sequencing methods - relying on a stepwise identification of suitably labelled nucleotides - are described in paragraph [0053] as being conventional techniques and thus, well-known in the art, and the steps of these (conventional, stepwise) sequencing methods appear to be, even though in a general manner, correctly described in paragraph [0054], regardless of the erroneous reference to the patent US-A-5634413 which anyway is cited therein as describing only a sequencing method similar to that, or to those, known (conventional, stepwise) method(s) that may be used in an embodiment of the invention.

25. Therefore, the amendment introduced on page 6 of the description on 24 September 2014 is in compliance with the requirements of Article 84 EPC.

Apportionment of costs (Article 104(1) EPC)

26. Since the oral proceedings scheduled for 8 October 2021 were cancelled by the board upon appellant's withdrawal of its request for oral proceedings, the respondent's conditional request for apportionment of costs, in line with respondent's response to the communication pursuant to Article 17 RPBA 2020, is deemed also to be withdrawn.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated