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Datasheet for the decision of 25 January 2024

Case Number: T 1692/21 - 3.3.08

Application Number: 17180803.3

Publication Number: 3260555

IPC: C12Q1/68, C12Q1/6806

Language of the proceedings: EN

Title of invention:
Novel protocol for preparing sequencing libraries

Patent Proprietor:
Verinata Health, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:
sequencing libraries/VERINATA HEALTH

Relevant legal provisions:
EPC Art. 56, 113(1)
EPC R. 106
RPBA 2020 Art. 13(2)

Keyword:
Amendment to appeal case (yes)
Inventive step (no) - closest prior art
Obligation to raise objections - objection dismissed

Decisions cited:
T 1459/11, T 0752/16, T 2843/19

Catchword:
-

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Case Number: T 1692/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 25 January 2024

Appellant: (Opponent)	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Simmons & Simmons LLP (Munich) Lehel Carré Thierschplatz 6 80538 Munich (DE)
Respondent: (Patent Proprietor)	Verinata Health, Inc. 5200 Illumina Way San Diego, California 92122 (US)
Representative:	Cooley (UK) LLP 22 Bishopsgate London EC2N 4BQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 July 2021 concerning maintenance of the European Patent No. 3260555 in amended form**

Composition of the Board:

Chair	T. Sommerfeld
Members:	B. Claes
	R. Winkelhofer

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies from the interlocutory decision of the opposition division that European patent No. 3 260 555 ("the patent"), as amended in the form of the main request, and the invention to which it relates met the requirements of the EPC. The patent entitled "*Novel protocol for preparing sequencing libraries*" had been granted on European patent application No. 17180803.3.

II. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(c) EPC. The opposition division held *inter alia* that the subject-matter of claim 1 of the main request involved an inventive step.

III. With the statement of grounds of appeal, the appellant argued, *inter alia*, that the decision under appeal was wrong with respect to inventive step.

IV. In the reply to the appeal, the patent proprietor (respondent) maintained the main request as well as auxiliary requests 1 and 2 (all filed with the submission of 16 December 2019) and defended the decision under appeal on, *inter alia*, inventive step.

V. The board issued a communication pursuant to Article 15(1) RPBA providing the board's preliminary assessment of substantive and legal matters concerning the appeal.

VI. Both parties replied to the board's communication.

VII. During the oral proceedings, the respondent raised the following objection under Rule 106 EPC in conjunction with Article 112a(2) EPC:

"*In accordance with Rule 106 EPC I hereby request that the Board of Appeal provide a Decision in respect of the infringement of the Respondent's rights to be heard in the above matter and which is in contravention of Article 113 EPC.*

As raised during the oral proceedings of 25 January 2023 [sic]*, it is the Respondent's position that the Appellant has not raised or substantiated a Ground of Appeal based on lack of inventive step of Auxiliary Requests 1 and 2 currently on file based upon D2 as the closest prior art.*

Section VIII of the Grounds of Appeal, paragraph 1 identifies D9 as the closest prior art. Section VIII paragraph 32 then begins the discussion of lack of inventive step for Auxiliary Requests 1 and 2. At no point in this paragraph or section or indeed in the Grounds of Appeal is it unambiguously stated that D2 is considered to represent the closest prior art for Auxiliary Requests 1 and 2. Accordingly, in the Respondent's view this Ground of Appeal has never been raised.

The Board of Appeal's Decision at the oral proceedings that this Ground has been substantiated, and provides the basis of a lack of inventive step for the claims of both Auxiliary Requests 1 and 2, therefore, presents the Respondent with a Ground of Appeal on which they have never had the opportunity to respond. This constitutes an infringement of the Respondent's right

to be heard in contravention of Article 113 EPC and which forms a valid ground for the Respondent to petition the Enlarged Board to review the Board of Appeal's Decision in accordance with Article 112a EPC."

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

D2: Z. Zheng *et al.*, Nucleic Acids Research, vol. 38, No. 13, e137 (2010), pages 1-9; published online at doi: 10.1093/nar/gkq332

D9: H.C. Fan *et al.*, Clinical Chemistry, vol. 56, No. 8 (2010), pages 1279-86 (including Supplemental Methods)

D10: G.J.W. Liao *et al.*, Clinical Chemistry, vol. 57, No. 1 (2011), pages 92-101

D11: "Preparing Samples for ChIP Sequencing of DNA" protocol published by Illumina (2007)

IX. The submissions and arguments of the parties in appeal are taken into consideration in the reasons for the decision below.

X. The appellant requests that the decision under appeal be set aside and amended such that the patent be revoked.

The respondent requests that the appeal be dismissed (main request) or the patent be maintained on the basis of auxiliary requests 1 or 2 submitted on 16 December 2019.

Reasons for the Decision

Main request - inventive step - claim 1

1. Claim 1 reads as follows:

> "1. A method for preparing a sequencing library from a test sample comprising nucleic acid molecules, wherein said nucleic acids are human cell-free DNA (cfDNA) molecules, wherein the method comprises the consecutive steps of end-repairing, dA-tailing and adaptor ligating said nucleic acids, wherein said consecutive steps exclude purifying the end-repaired products prior to the dA-tailing step and exclude purifying the dA-tailing products prior to the adaptor-ligating step, and wherein said consecutive steps are performed in less than 1 hour."

Closest prior art

2. The opposition division held that the disclosure in document D9 represented the closest prior art for the purpose of the assessment of inventive step by the problem-solution approach. Whereas document D9 disclosed the preparation of a sequencing library made from cell-free DNA (cfDNA), document D2 disclosed the reparation of a sequencing library of bacterial DNA. Thus document D9 served the same purpose as the claimed subject-matter and represented "*the most suitable spring board for assessing inventive step*". Having disqualified the disclosure in document D2 as closest prior art, the opposition division then stopped short of assessing whether the claimed subject-matter could be considered to involve an inventive step when starting from the Y-library preparation disclosed in

document D2, and only held that, when starting from the method disclosed in document D9, the claimed subject-matter would not be obvious to the skilled person and therefore involved an inventive step.

3. On appeal the appellant reiterated, however, that the teaching of the Y-library preparation disclosed in document D2 also represented a suitable starting point for assessing inventive step, and argued that the claimed subject-matter lacked inventive step when starting from this disclosure.

4. The respondent submitted that the opposition division had rightly held that document D9 represented the closest prior art and that the appellant had not convincingly demonstrated that the teaching of the Y-library preparation disclosed in document D2 represented an "*equally valid starting point to D9 for the assessment of inventive step*" (see point 6.22 of the reply to the appeal). Furthermore, document D2 disclosed three different library preparation methods, i.e. for Y-library preparation, for titanium-library preparation and for a simplified AB-library preparation (see Figure 1), and there was no teaching in document D2 to use the Y-library preparation. The appellant's choice of the Y-library preparation in document D2 as the closest prior art was therefore unfounded.

5. The patent and each of documents D2 and D9 originates from the same technical field of (automated) next-generation DNA sequencing methods and concerns methods for the preparation of sequencing libraries from test samples. Both documents therefore relate to a purpose similar to that of the claimed subject-matter and consequently constitute suitable disclosures for starting the assessment of inventive step. The same

applies *mutatis mutandis* to the three different library preparation methods disclosed in document D2.

6. In any case, it is an established principle in the case law of the Boards of Appeal (see "Case Law of the Boards of Appeal of the EPO", 10th edn., 2022 - in the following "CLBA" - I.D.3.2 and I.D.3.4) that the rationale of the problem-solution approach for assessing inventive step (Article 56 EPC) requires that the claimed invention not be obvious to a skilled person having regard to *any* teaching in the state of the art under Article 54(2) EPC. Accordingly, even if the appellant "chooses" as closest prior art a disclosure in a document which the respondent and/or the opposition division considers more remote from the claimed subject-matter than another document, such an attack cannot be disregarded solely on the basis that the document was not the most suitable starting point for discussing inventive step. By the same token, if inventive step is to be denied, the choice of starting point needs no specific justification.

7. Therefore, although document D9 may relate to the same kind of DNA sample as the claimed subject-matter (cfDNA), and its disclosure may or may not be considered "closer" to the claimed subject-matter, this does not *disqualify* other disclosures relating to a similar purpose, such as that of document D2, as a suitable starting point in assessing inventive step.

8. The disclosure of the Y-library preparation method in document D2 consequently constitutes such suitable starting point.

Technical difference, effect and problem

9. It is undisputed that the Y-library preparation method disclosed in document D2 (see paragraph bridging pages 3 and 4, Figure 1) includes the steps of end-repair by T4 DNA polymerase and T4 polynucleotide kinase ("*end polishing*"), dA-tailing by treatment with Klenow fragment exo- ("*dA extension*") and adaptor ligating ("*ligation*"). These method steps are consecutive and there are no purification steps between them ("*in one reaction without clean-up in between*").

10. The appellant held, and the respondent has not disputed, that the claimed subject-matter differed from the Y-library preparation method disclosed in document D2 in two aspects:

i) the nucleic acid sample consists of human cfDNA molecules, and

ii) the consecutive steps are performed in less than 1 hour.

11. The appellant submitted that the effects of each of these two differing features were not functionally interrelated and that therefore partial objective technical problems had to be formulated and assessed based on each effect separately.

12. According to the respondent, the partial-problem approach was not, however, appropriate for the case at hand, since the use of cfDNA and the time limitation requirement were directly associated with the preparation of a sequencing library that was defined by a distinctive content of sequences (cfDNA), as compared with those disclosed in document D2 (bacterial DNA),

and the two distinguishing features thus combined to provide an *improved* sequencing library that, in use, ultimately resulted in an improved sequencing method.

13. It is also established jurisprudence of the Boards of Appeal that the existence of a combination of features, i.e. of a combination invention, is to be viewed differently from the mere existence of partial problems, i.e. of an aggregation of features. In fact, partial problems exist if the features or sets of features of a claim are a *mere aggregation* of these features or sets of features (juxtaposition or collocation) which are *not functionally interdependent*, i.e. do not mutually influence each other to achieve a technical success over and above the sum of their respective individual effects, in contrast to what is assumed in the case of a combination invention (see CLBA, I.D.9.3.2).

14. The respondent's argument fails to convince that, in the context of the claimed method for preparing a sequencing library from a test sample, the use of cfDNA as the starting material and the time limitation requirement would be functionally interdependent, i.e. mutually influence each other to achieve a technical effect beyond the sum of the respective individual effects (see above). The board thus agrees with the appellant that the partial-problem approach is appropriate.

i) first partial objective technical problem

15. The appellant submitted that the enzymes used in the consecutive steps of the claimed method did not distinguish between the origins of the DNA in the sample used. Therefore the effect of the first

distinguishing feature was merely to provide a method for preparing a sequencing library applicable to a purified DNA of different origin, here human cfDNA. The partial objective technical problem was therefore the provision of a method for preparing a sequencing library which can be applied to human cfDNA.

16. The respondent submitted in this context that cfDNA was widely used in the art as an easily accessible genetic biomarker holding enormous utility for disease diagnosis and monitoring of copy number variations, single nucleotide polymorphisms and other mutations in e.g. cancer and foetal medicine. The effect attained was thus more than that formulated by the appellant.

17. However, the respondent's argument relates to the utility of the results ultimately obtained using the sequencing library prepared by the claimed method, and is thus divorced from the effect identified above and the objective technical problem to be solved. This argument must therefore fail.

18. The board therefore also agrees with the appellant on the formulation of the first partial objective technical problem (see point 15.).

ii) second partial objective technical problem

19. Further according to the appellant, the second distinguishing feature had the effect that a method for preparing a sequencing library as claimed was performed in a shorter time than with the Y-library preparation method disclosed in document D2. The partial objective technical problem was therefore the provision of a method for preparing a sequencing library in a shorter time.

20. The respondent submitted in this context that performing the consecutive steps of end-repairing, dA-tailing and adaptor ligating in less than one hour as required by claim 1 had the effect of providing a rapid diagnostic service in the context of cfDNA (see patent in suit, paragraph [0216]).

21. However, here too, the respondent's argument in fact relates to the utility of the results eventually obtained using the sequencing library prepared by the claimed method (see point 17.), and the argument must therefore also fail.

22. The board therefore agrees with the appellant on the formulation of the second partial objective technical problem too (see point 19.).

Obviousness

i) in the context of the first partial problem

23. Having regard to the first partial objective technical problem at hand for which the skilled person was seeking a solution, i.e. providing a method for preparing a sequencing library which can be applied to human cfDNA, it needs to be established whether the skilled person would have deemed the Y-library preparation method disclosed in document D2 suitable for use with human cfDNA test samples.

24. The board agrees with the appellant that, since the enzymes used in the consecutive steps of the Y-library preparation method disclosed in document D2 could not distinguish between the origins of the DNA in the sample used, human cfDNA was merely an arbitrary choice

of an alternative DNA source as the starting material for the Y-library preparation method disclosed in document D2 over the bacterial DNA model test samples used in the experiments described in document D2 to test new methods for preparing sequencing libraries. In fact, standard protocols for purification of cfDNA were commercially available which required no technical adaptation as a test sample in the Y-library preparation method described in document D2 and hence for preparing the purified human cfDNA sample as starting material in the claim (see example 1 of the patent). The skilled person could thus reasonably expect the Y-library preparation method to be suitable for application to human cfDNA test samples.

25. The appellant further submitted that the disclosure in document D2 that the described methods were useful for "*trace amounts of starting material such as precious clinical samples, transcriptomes of small tissue samples and metagenomics on low biomass environments*" (see last sentence of the abstract) provided the skilled person with an incentive to use, for example, human cfDNA, being DNA from a clinical sample, as an obvious alternative DNA test sample for preparing a sequencing library following the protocols of document D2.

26. The respondent noted, however, that document D2 did not suggest that the disclosed sequencing library preparation methods could work with human cfDNA. Moreover, the term "precious clinical samples" in the passage cited by the appellant was not necessarily understood by the skilled person to mean "cfDNA", but rather to refer to material obtained from biopsies and the like. Even the suggestion at the end of the discussion section of document D2 of a potential

application of the methods to metazoan or plant genomes was expressly qualified by the statement that "*further validation studies might be needed*" (see page 8, right-hand column, last paragraph). Document D2, therefore, lacked any pointer to using the disclosed methods for preparing a sequencing library preparation of human cfDNA.

27. The board, however, agrees with the appellant that the cited passage in document D2 can also not reasonably be interpreted as advice *against* the described sequencing library preparation methods being suitable used for cfDNA test samples.

28. The respondent, lastly, further argued that the DNA test samples used in the sequencing library preparation methods of document D2 contained 1 ng of bacterial DNA, nebulised and selected for fragment sizes between 300 and 800 bp (see page 3, left-hand column, lines 2 to 12 of document D2). However, cfDNA was distinct from bacterial DNA and by nature also smaller than 300 bp (see patent, paragraph [0122] on page 18, lines 3 to 11; see document D9, which reported that human cfDNA had a peak size of approximately 160 to 180 bp, page 1279, section "RESULTS", and page 1285, left-hand column, lines 9 to 11; see also document D10). Indeed, as could be concluded from the graphs in Figures 7A and 7B of the patent, no fragments in the size range between 300 and 800 bp were actually detected in the cfDNA sequencing library preparations disclosed in the patent. According to the respondent, document D2 thus *excluded* DNA fragments smaller than 300 bp and focused on preparing sequencing libraries for test samples of larger DNA sizes. Therefore the skilled person would need to technically deviate from the teaching in

document D2 when using cfDNA in the disclosed preparation methods.

29. In this aspect too, the board agrees with the appellant that, for the purpose of the experiments described in document D2, DNA of bacterial origin was merely used to prepare standardised model DNA test samples for testing and validating the disclosed methods for preparing sequencing libraries. The described fragmentation (nebulisation) and size selection between 300 and 800 bp of the bacterial DNA (page 3, left-hand column, lines 2 to 12) resulted in particular and defined model test samples, but cannot reasonably be interpreted as *excluding* the utility of the disclosed Y-library preparation method for other DNA size ranges, as suggested by the respondent.

30. In view of the above considerations, the board concludes that, with a view to finding a solution to the first partial objective technical problem, the claimed method for preparing a sequencing library from a test sample comprising human cfDNA was obvious to the skilled person.

ii) in the context of the second partial problem

31. In the Y-library preparation method disclosed in document D2, end-repair and dA-tailing are performed within 40 minutes without clean-up (see page 3, section "*Y library*", "*at 12°C for 10 min, 37°C for 10 min, 72°C for 20 min*"). The subsequent adaptor ligation was performed overnight at 12°C (see page 4, left-hand column, lines 1 to 2).

32. The appellant submitted, and the board agrees, that, with the introduction of modern high-throughput

processes such as automated next-generation DNA sequencing methods, the need to speed up the processes was inherent and imperative, including reducing the time needed to generate appropriate sequencing libraries. The skilled person would thus also have looked for options to speed up performing the Y-library preparation method disclosed in document D2.

33. Figure 1 of document D2, a "*schematic description of three types of library construction*" (see legend), outlines the key features of, *inter alia,* the disclosed Y-library preparation method. The length of the dA-tail adaptor ligation (overnight) is not mentioned, and thus not qualified, as a key feature of the method relevant to achieving the observed effect. Therefore, when looking for options to speed up the Y-library preparation method, shortening the adaptor ligation reaction time would be such an option for the skilled person without technically having to deviate from the key features of the teaching disclosed in document D2.

34. In view of the motivation of the skilled person outlined above, the respondent's argument that there was no teaching or suggestion that any of the library preparation methods disclosed in document D2 should be performed in less than one hour as opposed to including an "overnight" ligation in the AB-library and Y-library preparation methods (see pages 3 and 4, sections "*AB library*" and "*Y library*") is not pertinent.

35. The skilled person would find guidance for the option of shortening the adaptor ligation reaction time in the known and commercially available standard sequencing library preparation protocols for DNA samples provided by Illumina, such as disclosed for instance in documents D9 and D11, in which the adaptor ligation to

dA-tailed double stranded DNA fragments (as is also part of the Y-library preparation method of document D2 and the claimed method) is routinely performed over 15 minutes (see document D9, page 1280, section "*sequencing library construction*", which protocol corresponds in its relevant parts to the disclosure in paragraph [0212] of the patent, which includes on page 37, line 10, the 15-minute ligation step; and document D11, on page 4 "*Workflow*" and on page 9 section "Ligate Adapters to DNA Fragments", "Procedure", point 3).

36. When this 15 minute-adaptor ligation is implemented in the Y-library preparation method disclosed in document D2, the time required to prepare the sequencing library is only 55 minutes, i.e. less than one hour, as is indeed also corroborated by the same time needed in the patent in suit for the "abbreviated protocol" disclosed in Example 2.

37. In view of the above considerations, the board also agrees with the appellant that the claimed solution to the second partial objective technical problem of providing a method for preparing a sequencing library in a shorter time, i.e. where the "*consecutive steps are performed in less than 1 hour*", when starting from the Y-library preparation method disclosed in document D2 representing the closest prior art, was also obvious to the skilled person when taking into account the teachings in, *inter alia*, documents D9 and/or D11.

Conclusion (inventive step of the main request)

38. The claimed subject-matter would be obvious to the skilled person in both aspects and, accordingly, lacks inventive step (Article 56 EPC).

Auxiliary requests 1 and 2 – inventive step – claim 1

39. Claim 1 of auxiliary request 1 reads (amendments by insertion over claim 1 of the main request are underlined):

"1. A method for preparing a sequencing library from a test sample comprising nucleic acid molecules, wherein said nucleic acids are human cell-free DNA (cfDNA) molecules <u>from a maternal plasma sample</u>, wherein the method comprises the consecutive steps of end-repairing, dA-tailing and adaptor ligating said nucleic acids, wherein said consecutive steps exclude purifying the end-repaired products prior to the dA-tailing step and exclude purifying the dA-tailing products prior to the adaptor-ligating step, <u>wherein said nucleic acids are not subjected to fragmentation prior to the consecutive steps of end-repairing, dA-tailing and adaptor ligating said nucleic acids</u> and wherein said consecutive steps are performed in less than 1 hour."

Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 1, with the insertion of the wording "and in the same reaction tube" at the end.

40. In the reply to the appeal, the respondent's submission was limited regarding auxiliary request 1 to stating that "*the claimed subject-matter is inventive for at least the reasons provided above for the Main Request*" (see point 9.2 of the reply to the appeal). No

further arguments were presented as to why the amendments in claim 1 of auxiliary request 1 would result in the claimed subject-matter involving an inventive step when starting from the disclosure in document D2, in particular as to the alleged technical effects of the newly-introduced features and what difference they would make to the assessment of inventive step.

41. No relevant difference has thus been shown, and such cannot be seen either. In view of this alone, the subject-matter of claim 1 of auxiliary request 1 likewise does not, *mutatis mutandis*, involve an inventive step.

42. The respondent also limited the submission in the reply to the appeal regarding auxiliary request 2 to stating that *"the claimed subject-matter is inventive for at least the reasons provided above for Auxiliary Request 1*" (see point 13.2 of the reply to the appeal).

43. As a consequence, the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step either, for the same reasons as set out in the context of claim 1 of auxiliary request 1 when starting from the disclosure in document D2 (see points 40. and 41.).

44. Furthermore, the feature that the consecutive steps referred to in claim 1 of auxiliary request 2 are performed in the same reaction tube is also a feature of the Y-library preparation taught in document D2, representing the closest prior art, and thus cannot contribute to the inventive character of the claimed subject-matter.

Admittance and consideration of the respondent's submissions on inventive step of 11 December 2023

45. In the communication pursuant to Article 15(1) RPBA (see section V.), the board expressed the considerations discussed in points 40. to 44. above, as a preliminary opinion on inventive step in respect of auxiliary requests 1 and 2 (see points 27 to 31 of the communication).

46. In response to the board's communication, the respondent filed a further submission on 11 December 2023 (see section VI.) providing arguments dedicated to inventive step of the claimed subject-matter of the auxiliary requests (notably, on closest prior art, the technical problems and their solutions).

47. The submission (see also point 51. below) is an amendment to the respondent's case and its admission is governed by Article 13(2) RPBA, which imposes the most stringent limitations on a party wishing to amend its appeal case at an advanced stage of the proceedings, and provides that any amendment to a party's appeal case made at this stage of the proceedings will not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons.

48. The respondent submitted therein that it was "*in direct response to statements made by the Board of Appeal in its preliminary opinion, which demonstrate an erroneous approach to apply inventive step as a ground of opposition to Auxiliary Requests 1 and 2. This creates an exceptional circumstance, justified herein with cogent reasons, in which these further submissions should be taken into account as a result (Article 13(2)*

RPBA)." The essence of the respondent's argument in this respect was that "*when considering the choice of closest prior art, rather than assess claim 1 of Auxiliary Request 1 afresh, so analysing the purpose, effect and relevant technical features of the claimed subject matter as a whole, the Board has simply assumed that D2 should remain the closest prior art and then considered the further technical features recited in claim 1 of Auxiliary Request 1 in isolation. Such an assessment is subjective, lacks legal basis and is hence fundamentally flawed*" (see point 2.12 of the respondent's submission of 11 December 2023). A similar argument applied to auxiliary request 2 (see point 3.5). The respondent argued along these lines during the oral proceedings as well.

49. Arguments that, for the purpose of the assessment of inventive step of the subject-matter of claim 1 of the main request, the Y-library preparation method disclosed in document D2 represented a suitable starting point for assessing inventive step, and when starting from this closest prior art the claimed subject-matter would be obvious to the skilled person, were part of the appeal proceedings by virtue of the appellant's submissions in the grounds of appeal (see points V.4 to V.48 of the grounds of appeal). The appellant also argued in the grounds of appeal that the subject-matter of claim 1 of the auxiliary requests lacked inventive step (see points VIII.32 to VIII.36 of the grounds of appeal).

50. Although the appellant did not explicitly repeat (or as the respondent submitted "*unambiguously stated*"), in the context of auxiliary requests 1 and 2, that they started from the Y-library preparation method disclosed in document D2 representing the closest prior art, it

is implicit from its content that the appellant's submission started from the same closest prior art and partial objective technical problems as had been formulated for the subject-matter of claim 1 of the main request.

51. Accordingly, the arguments provided in the submission of 11 December 2023 ought already to have been part of the respondent's reply to the appeal (Article 12(3) RPBA). By the same token, it could not have surprised the respondent that the board in the communication, contrary to the opposition division, agreed with the appellant's choice of closest prior art for assessing inventive step of the subject-matter of the main request *and* of the auxiliary requests.

52. With regard to Article 13(2) RPBA, it is irrelevant whether the board's communication differs from the contested decision. An unfavourable preliminary opinion for a party can, in principle, be expected at any time in the proceedings before a decision is handed down. In fact, it is pointed out in this context that the communication of a preliminary opinion under Article 15(1) RPBA 2020 is primarily a procedural measure aimed at facilitating the preparation of the parties for possible oral proceedings, and does not imply an "invitation" to further amendments in response (see e.g. decisions T 752/16, point 3.4, and T 1459/11, point 3.2).

53. It is further incumbent on the parties to submit their arguments in the proceedings in good time, in order for them to be taken into account already in the board's communication. The parties have a duty to conduct appeal proceedings diligently and expeditiously, for reasons of fairness to the other parties, but also to

bring the proceedings to an end within a reasonable period of time. Article 13(2) RPBA 2020 sanctions this duty to contribute to swift conduct of the appeal proceedings, and thus the obligation, in the case at hand, to submit any line of argument as to inventive step in good time before the communication (see decision T 2843/19, point 3.3). This has not happened in the case at hand.

54. Therefore there are no exceptional circumstances warranting taking into account the respondent's submission of 11 December 2023 (Article 13(2) RPBA).

Conclusion (inventive step of the auxiliary requests)

55. The subject-matter of claim 1 of both auxiliary requests 1 and 2 does not involve an inventive step (Article 56 EPC) for the reasons in points 40. to 44. above.

Objection under Rule 106 EPC in conjunction with Article 112a(2) EPC

56. During the oral proceedings, the respondent raised an objection under Rule 106 EPC in conjunction with Article 112a(2)(c) EPC (see section VII.).

57. The objection concerns the board's decision not to admit and consider the arguments of the respondent's submission of 11 December 2023 on appeal (see points 45. to 54. above). The respondent expresses the view that "*At no point ... in the Grounds of Appeal is it unambiguously stated that D2 is considered to represent the closest prior art for Auxiliary Requests 1 and 2.*"

58. This very argument had to be rejected, for the reasons outlined in point 50. above. Accordingly, no violation of the appellant's right to be heard under Article 113(1) EPC has occurred.

59. Therefore the objection under Rule 106 EPC in conjunction with Article 112a(2) EPC was to be dismissed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated