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Datasheet for the decision of 24 May 2024

Case Number: T 0972/22 - 3.3.08

Application Number: 14727479.9

Publication Number: 3004349

IPC: C12N15/10, C12N15/82, C12N15/85, C12N15/90, A01K67/00

Language of the proceedings: EN

Title of invention:
A METHOD FOR PRODUCING PRECISE DNA CLEAVAGE USING CAS9 NICKASE ACTIVITY

Patent Proprietor:
Cellectis S.A.

Opponent:
Strawman Limited

Headword:
DNA acleavage using cas9 nickase/CELLECTIS

Relevant legal provisions:
EPC Art. 56, 113(1)
EPC R. 99(1), 103(1), 111(2)
RPBA 2020 Art. 11

Keyword:

Admissibility of appeal (yes)
Main request - inventive step (no)
Substantial procedural violation (yes)
Right to be heard - opposition procedure - refusal to file further auxiliary requests - appealed decision sufficiently reasoned (no)
Third-party observations - not addressed in communications by the opposition division
Remittal - special reasons for remittal - fundamental deficiency in first-instance proceedings (yes)
Reimbursement of appeal fee - equitable by reason of a substantial procedural violation (yes)

Decisions cited:

T 0012/07, T 1968/08, T 1756/11, T 1758/15, T 0894/19

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Case Number: T 0972/22 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 24 May 2024

Appellant: (Patent Proprietor)	Cellectis S.A. 8, rue de la Croix Jarry 75013 Paris (FR)
Representative:	Casalonga Bayerstraße 71/73 80335 München (DE)
Respondent: (Opponent)	Strawman Limited Orchard Lea Horns Lane Combe, Witney Oxfordshire OX29 8NH (GB)
Representative:	Greaves Brewster LLP Copa House Station Road Cheddar, Somerset BS27 3AH (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 25 February 2022 revoking European patent No. 3004349 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chair	T. Sommerfeld
Members:	B. Claes
	G. Decker

Summary of Facts and Submissions

I. The appeal lodged by the patent proprietor (appellant) lies from the decision of the opposition division to revoke European patent No. 3 004 349. The patent with the title "*A method for producing precise DNA cleavage using Cas9 nickase activity*" was granted for European patent application No. 14727479.9.

II. The opposition division decided, *inter alia,* that claim 1 of the patent as granted (main request) related to added subject-matter (Article 100(c) EPC) and that the subject-matter of claim 1 of auxiliary request 1 lacked an inventive step (Article 56 EPC).

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

D2: Cong *et al.*, Science 339(6121), 2013 819-23

D25: Mali *et al.*, Science 339(6121), 2013 823-26

IV. With the statement of grounds of appeal, the appellant re-submitted the set of claims of auxiliary request 1 dealt with in the decision under appeal as the new main request and submitted sets of claims of 13 new auxiliary requests and an amended description.

Claim 1 of the main request reads:

"1. An in vitro method for precisely inducing a nucleic acid cleavage in a genetic sequence in a cell comprising:

(a) Selecting a first and second double-stranded nucleic acid target in said genetic sequence, each nucleic acid target comprising, on one strand, a protospacer adjacent motif (PAM) at one 3' extremity;
(b) engineering two CRISPR targeting RNAs (crRNAs) comprising each:
- a sequence complementary to one part of the opposite strand of the nucleic acid target that does not comprise the PAM motif, and
- a 3' extension sequence;
(c) providing at least one trans-activating CRISPR targeting RNA (tracrRNA) comprising a sequence complementary to one part of the 3' extension sequences of said crRNAs under b);
(d) providing at least one cas9 nickase which is a cas9 nuclease harboring either a non-functional RuvC-like or a non-functional HNH nuclease domain and recognizing said PAM motif(s);
(e) introducing into the cell said crRNAs, said tracrRNA(s) and said Cas9 nickase; wherein the cell is a primary T-cell,
such that each Cas9-tracrRNA:crRNA complex induces a nick event in double-stranded nucleic acid targets in order to cleave the genetic sequence between said first and second nucleic acid targets."

V. By letter dated 20 October 2022, the appellant provided information on "*the address of the appellant: Cellectis*".

VI. With the reply to the appeal, the opponent (respondent) filed six new documents.

VII. Further submissions were made by the parties, accompanied by new documents, new claim requests and two amended versions of the patent description.

VIII. In a further letter, the respondent made submissions on the admittance of the auxiliary requests.

IX. In a submission dated 7 May 2024, the appellant requested "*that the proceedings be stayed until the decision* [in case T 439/22] *is rendered, or at least that the oral proceedings be reported* [sic] *until the questions referred to the EBA be published, to decide on such a stay*".

X. The board informed the parties that the oral proceedings scheduled for 24 May 2024 would take place as scheduled.

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

XII. The parties' requests relevant for the decision of the board were as follows.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that:
- the patent be maintained on the basis of the set of claims of the main request (auxiliary request 1 in the decision under appeal), or that:
- the case be remitted to the opposition division for further prosecution *"unless the board can confirm in writing the preliminary analysis of the OD on* [sufficiency of disclosure]" or, alternatively, that:
- the patent be maintained on the basis of the set of claims of one of auxiliary requests 1 to 13 (where auxiliary requests 1 to 7 correspond, respectively, to auxiliary requests 2 to 7 and 1 as filed with the

grounds of appeal) or one of auxiliary requests 14 to 27, filed with the submission of 10 March 2023.

The appellant further requested that:
- the appeal fee be reimbursed due to a substantial procedural violation
- claim 1 of the main request be interpreted on the basis of the amended description filed together with the main request should claim 1 of the main request be interpreted in view of the description of the patent specification
- the proceedings be stayed in view of the envisaged referral to the Enlarged Board of Appeal in case T 439/22 should the amended description according to the main request not be admitted into the proceedings.

The respondent (opponent) requested that:
- the appeal be dismissed
- auxiliary requests 1 to 27 not be admitted into the proceedings
- the case not be remitted to the opposition division for further prosecution
- the amended description not be relied on when interpreting claim 1 of the main request
- the proceedings not be stayed in view of the envisaged referral to the Enlarged Board of Appeal in case T 439/22.

Reasons for the Decision

Admissibility of the appeal (Rule 99(1)(a) and (c) EPC)

1. Under Rule 101(1) EPC, if the appeal does not comply with Articles 106 to 108, Rule 97 or Rule 99(1)(b) or

(c) or Rule 99(2) EPC, the board must reject it as inadmissible unless any deficiency has been remedied before the relevant period under Article 108 EPC has expired. Furthermore, in accordance with Rule 101(2) EPC, if the board notes that the appeal does not comply with Rule 99(1)(a) EPC, it must communicate this to the appellant and invite it to remedy the deficiencies noted within a period to be specified. If the deficiencies are not remedied in due time, the board must reject the appeal as inadmissible.

2. According to the respondent, the requirements of Rule 99(1) EPC that the notice of appeal must contain (paragraph (a)) the name and the address of the appellant as provided in Rule 41, paragraph 2(c) and (paragraph (c)) a request defining the subject of the appeal were not met.

3. In the context of Rule 99(1)(a) EPC, the respondent submitted that only after filing the statement of grounds of appeal (see section V.) were the name and address of the appellant identified. However, the name given in said submission, "Cellectis", was different to the name of the patent proprietor according to the EPO register, listing the patent proprietor as "Cellectis S.A.". It was therefore unclear how Cellectis, the initial "appellant", was adversely affected by the decision under appeal and had standing to file an appeal.

4. In the notice of appeal, the name "Cellectis S.A." identified the patent proprietor in the subject field. The same is true for the subsequent letter providing the address of the appellant. The fact that in the body of this letter the address is preceded by the name "Cellectis" is therefore evidently a mere (erroneous or

deliberate) omission of the legal form "S.A." of the company "Cellectis S.A." and cannot raise doubts as to the identity of the appellant.

5. In the context of Rule 99(1)(c) EPC, the respondent submitted that the notice of appeal contained no request defining the subject of the appeal but merely requested that the "*decision be set aside*", without identifying which aspect(s) were appealed.

6. In its notice of appeal, the appellant requested that the decision under appeal be set aside and identified the appealed decision. It is established case law of the Boards of Appeal (see Case Law of the Boards of Appeal of the European Patent Office, 10th edn., 2022 (CLBA), section V.A.2.5.2 c) and further references cited there) that the requirement under Rule 99(1)(c) EPC is met where the notice of appeal states that "an appeal is filed" or contains a request to set aside the decision as a whole. Such requests have the effect of "defining the subject of the appeal" within the meaning of Rule 99(1)(c) EPC. It is not necessary for a patent proprietor to include in the notice of appeal a request for maintenance of the patent in any particular form. This is something which relates to "the extent to which [the decision] is to be amended" and which is therefore a matter for the statement of grounds of appeal under Rule 99(2) EPC.

7. This request thus defines the subject of the appeal, as required by Rule 99(1)(c) EPC.

8. The appeal of the patent proprietor is thus admissible.

Main request - claim 1

Inventive step (Article 56 EPC) - claim 1

9. Claimed is an *in vitro* method for precisely inducing a nucleic acid cleavage in a genetic sequence in a primary T-cell by inducing a nick event in a first and second double-stranded nucleic acid target in the genetic sequence by at least one engineered Cas9 nickase-tracrRNA:crRNA complex to cleave the genetic sequence between the first and second nucleic acid targets.

Closest prior art

10. The opposition division decided that the subject-matter of claim 1 of auxiliary request 1 before it (i.e. the current main request) lacked an inventive step (Article 56 EPC) when starting from the disclosure in document D2, representing the closest prior art, in combination with the teaching of document D25 (see point 50 of the appealed decision).

11. The board agrees with the opposition division that the disclosure in document D2 represents the closest prior art for the assessment of inventive step, and, on appeal, the parties have not challenged this choice.

12. Document D2 is in the technical field of multiplex genome engineering and seeks to harness the type II prokaryotic clustered regularly interspaced short palindromic repeats (CRISPR) adaptive immune system to introduce targeted double-stranded breaks (DSBs) in mammalian chromosomes through heterologous expression of the key components. This is summarised in the abstract: "*We engineered two different type II CRISPR*

systems and demonstrate that Cas9 nucleases can be directed by short RNAs to induce precise cleavage at endogenous genomic loci in human and mouse cells. Cas9 can also be converted into a nicking enzyme to facilitate homology-directed repair with minimal mutagenic activity. Finally, multiple guide sequences can be encoded into a single CRISPR array to enable simultaneous editing of several sites within the mammalian genome, demonstrating easy programmability and wide applicability of the CRISPR technology."

13. Document D2 discloses the development of a number of precision genome-engineering tools based on the RNA-guided Cas9 nuclease (caspase) from the type II prokaryotic CRISPR adaptive immune system (see page 1, left-hand column, lines 8 to 22). The appellant agreed that at least four tools are disclosed:

tool (i): a codon-optimised *S. pyogenes* Cas9 nuclease (SpCas9) fused to nuclear localisation signals, ensuring nuclear compartmentalisation in mammalian cells enabling (specifically targeted) genome modification in mammalian cells (see page 1, left-hand column, line 22 to right-hand column, line 45)

tool (ii): a chimeric crRNA-tracrRNA hybrid, in which a mature crRNA is fused to a partial tracrRNA via a synthetic stem loop to mimic the natural crRNA:tracrRNA duplex for use with Cas9 in a two-component system (see page 1, right column, line 49 to page 2, left-hand column, line 4)

tool (iii): a DNA nickase (SpCas9n) derived from *S. pyogenes* Cas9 (resulting from an aspartate-to-alanine substitution at position 10 in the RuvC I domain of SpCas9); the nickase is shown to be useful

for targeted genome insertion through homology-directed repair (HDR) of a repair template (see page 2, left-hand column, lines 17 to 36)

tool (iv): multiple guide sequences encoded in a single crRNA array (here two arrayed spacers) targeting different regions in the mammalian genome which enables multiplexed genome engineering by simultaneous editing of several sites within the mammalian genome, exemplified by targeted deletion of larger genomic regions through concurrent DSBs (see abstract, lines 8 to 11 and page 2, left-hand column, lines 37 to 45)

Technical difference(s) and effect(s)

14. The board agrees with the appellant that the claimed subject-matter differs from the *in vitro* RNA-guided site-specific DNA cleavage based on Cas9 nucleases disclosed in document D2 in two aspects, namely that:

(a) the cleavage is performed with a nickase instead of a SpCas9 nuclease (caspase)

(b) the cleavage is performed in a primary T-cell instead of mammalian cells

15. The board agrees with the appellant that the technical effect of difference (a) is the *increased specificity* for creating a DSB in a genetic sequence in a cell.

16. The effect of difference (b) is that the engineering tools based on the RNA-guided Cas9 nuclease from the type II prokaryotic CRISPR adaptive immune system disclosed in document D2 were applied in mammalian cells limited to a primary T-cell.

17. It is established case law 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. 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, section I.D.9.3.2).

18. The technical effects of each of these two differing features (a) and (b) are functionally neither interrelated nor interdependent, and the appellant has not argued differently. Accordingly, to assess whether the claimed subject-matter involves an inventive step, two partial objective technical problems (partial-problem approach) have to be formulated based on each effect separately, and obviousness must be assessed for each partial problem.

Objective technical problem - partial problems

(a) first partial objective technical problem

19. Based on the technical effect of difference (a) (see point 15.), the board agrees with the appellant's formulation of the first partial objective technical problem as providing a method (using the CRISPR/Cas9 system) for inducing a DSB with improved specificity in a target genomic sequence. The board considers that the claimed subject-matter provides a solution to this

problem. Indeed, to produce a DSB, the RNA-guided Cas9 nuclease disclosed in document D2 uses a single target-specific sequence, whereas the double-nick event referred to in the claim uses two target-specific sequences.

(b) second partial objective technical problem

20. Neither the opposition division nor the respondent were able to identify from the disclosure in the patent any surprising effect associated with the application of the engineering tools disclosed in document D2 particularly in primary T-cells over other cell types which can be modified by the claimed method (see paragraphs [0043] to [0048] of the patent).

21. The appellant submitted for difference (b) that, while the skilled person was well aware that established cell lines as disclosed in document D2 could easily be used to test new tools, primary T-cells were used in cell therapy and therefore needed to be modified with sufficient certainty and safety. However, the appellant's argument pertains to the cells resulting from the claimed method and their further use, not to e.g. particular difficulties encountered when performing the engineering tools disclosed in document D2 on primary T-cells. The argument is therefore not related to an effect of relevance for formulating the technical problem.

22. Based on the technical effect of difference (b) (see point 16.), the opposition division and the respondent formulated the second partial objective technical problem as the provision of an alternative cell type for inducing precise nucleic acid cleavage in a genetic sequence. The board agrees with this formulation. The

board is also satisfied that the claimed subject-matter provides a solution to this problem.

Obviousness

(a) in the context of the first partial problem

23. To precisely induce a nucleic acid cleavage in a genetic sequence in a cell, the claimed *in vitro* method mechanistically requires only two nicking events to occur in a genetic sequence of a cell at first and second double-stranded nucleic acid targets to achieve the technical effect of cleaving the genetic sequence between the first and the second nucleic acid targets. The position of the two nicking events and the first and second double-stranded nucleic acid targets are not further detailed or defined in the claim.

24. It thus needs to be established whether it would have been obvious for the skilled person, having regard to the disclosure in document D2 and with a view to improving the specificity of the cleavage over the use of a SpCas9 nuclease (caspase), to use two nicking events in the genetic sequence for precisely inducing a DSB in a genetic sequence.

25. Concerning the multiplexed editing within a single genome and tool (iv) developed in that context, document D2 discloses, *inter alia*, that "*[u]sing a single CRISPR array encoding a pair of EMX1- and PVALB-targeting spacers, we detected efficient cleavage at both loci (Fig. 4F). We further tested targeted deletion of larger genomic regions through concurrent DSBs using spacers against two targets within EMX1 spaced by 119-bp* [...] *thus demonstrating the CRISPR*

system can mediate multiplexed editing within a single genome" (see page 2, left-hand column, lines 39 to 45).

26. Accordingly, document D2 teaches, besides the *in vitro* RNA-guided site-specific DNA cleavage based on Cas9 nucleases, multiplexed editing within a single genome with cas9 nucleases engineered to recognise two particular double-stranded nucleic acid targets.

27. Furthermore, in the context of the disclosed DNA nickase (SpCas9n) derived from *S. pyogenes* Cas9 (tool (iii)), document D2 discloses that the authors "*engineered an aspartate-to-alanine substitution (D10A) in the RuvC I domain of SpCas9 to convert the nuclease into a DNA nickase* [...]. [They] *then tested Cas9-mediated HDR at the same EMX1 locus with a homology repair template* [...]. *SpCas9 and SpCas9n catalyzed integration of the repair template into EMX1 locus at similar levels* [...]. *These results demonstrate the utility of CRISPR for facilitating targeted genomic insertions*" (see page 2, left-hand-column, lines 20 to 33).

28. Document D2 thus teaches a cas9 nuclease harbouring a non-functional RuvC-like nuclease domain (cas9 nickase) in accordance with step (d) of claim 1 engineered to recognise a particular double-stranded nucleic acid target (steps (a) to (c) of claim 1) and induce a nick event in the double-stranded nucleic acid target in a mammalian cell (step (e) of claim 1).

29. It is commonly known in the technical field that a DSB in a genetic sequence can be achieved, *inter alia,* by the induction of a double-stranded cut of a particular nuclease (e.g. resulting in blunt ends in the case of cas9 nucleases or sticky ends in the case of

restriction enzymes) or, as an alternative, by separately inducing two nicking events in opposite stands of the genetic sequence. Having regard to the teaching in document D2 of the tools for multiplexed editing within a single genome and the teaching of cas9-based nickases, the board judges that document D2 provides the skilled person with the necessary means and tools to arrive at the known alternative to the use of nucleases for achieving a DSB in a genetic sequence, i.e. the claimed induction of two nicking events in a genetic sequence of a cell at first and second double-stranded nucleic acid targets to cleave the genetic sequence between the first and the second nucleic acid targets.

30. Accordingly, when embarking on providing a method for inducing a DSB in a target genomic sequence, alternative to using cas9 nuclease, the skilled person would have arrived at the claimed subject-matter in an obvious manner based on the teachings in document D2 alone.

31. The appellant argued that because document D2 taught the use of multiple guide RNAs only to guide the Cas9 nucleases in two specific situations each with different and specific purposes, i.e. depending on the relative location of the targets, multiple targeting of Cas9 led either to multiplexed editing or to deletion of a large sequence but not to the use of a crRNA array with the aim of increasing Cas9 specificity or with a Cas9 nickase. Hence, document D2 did not motivate the skilled person to arrive at the claimed subject-matter. However, in view of the above considerations, the board is not persuaded by these arguments.

32. The board is furthermore not convinced by the appellant's further argument that because document D2 only tested the ability of a Cas9 nickase to enhance HDR in the presence of a repair template, thus avoiding DSBs and subsequent repair by non-homologous end joining (NHEJ, see page 2, left-hand column, lines 17 to 20), document D2 taught away from introducing a DSB for targeted modification of genomes. Indeed, for assessing obviousness of the claimed subject-matter for the first partial technical problem, the very aim is to induce a DSB in a genetic sequence, and therefore the argument must fail.

33. It is established case law of the Boards of Appeal (see CLBA, section I.D.10.8) that if, having regard to the state of the art, it had been obvious for a skilled person to arrive at something falling within the terms of a claim, additional or extra effects inevitably achieved by the obvious measures constitute a "bonus effect" which cannot support inventive step.

34. In the case in hand, by using a respective nickase to induce nicks at *two* different double-stranded nucleic acid targets as opposed to one target in the case of the cas9 nuclease, the resulting DSB is evidently obtained with an improved specificity in the target genomic sequence as two targeting guide RNAs (crRNAs) are employed as opposed to one in the case of the cas9 nuclease. The attained improved specificity of precisely inducing the nucleic acid cleavage therefore constitutes a "bonus effect" unable to support inventive step in this aspect of the claimed subject-matter.

(b) in the context of the second partial problem

35. The respondent agreed with the opposition division that the claimed subject-matter was rendered obvious to the skilled person by the combination of the teachings in documents D2 and D25.

36. Document D2 confirms that the *S. pyogenes* CRISPR system can be heterologously reconstituted in mammalian cells to facilitate efficient genome editing and teaches that another study (disclosed in document D25) had independently confirmed high efficiency CRISPR-mediated genome targeting in several human cell lines (see page 2, left-hand column, lines 47 to 51, reference 28 being document D25 in these proceedings).

37. Document D25 discloses the use of the CRISPR/Cas system for genomic modification (see e.g. page 2, last paragraph) in 293T cells (human embryonic kidney cells), K562 cells (human chronic myelogenous leukaemia cells) and PGP1-iPS cells (human induced pluripotent stem cells).

38. The opposition division considered, and the respondent agreed, that given that document D25 discloses the use of the CRISPR/Cas system for modifying the K562 (white blood) cell line, the document would have rendered the application of the system in primary T-cells obvious for the skilled person.

39. The board concurs with the respondent that the selection of a different cell type for carrying out the known methods of document D2 cannot justify acknowledging inventive step. Indeed, in the absence of any surprising effect attributable to the exemplified cell type as compared to the mammalian cell type(s)

used in document D2 and having regard to the teaching in document D25 that the CRISPR/Cas system for genomic modification can be used in different types of cells, including white blood cells, such a selection merely amounts to an arbitrary selection from a number of equally likely alternatives of white blood cells which thus would not involve an inventive step.

40. The appellant has restricted its written submissions on document D25 to noting that the document (i) disclosed a Cas9 nuclease guided by custom guide RNA (gRNA) (a two-component system) which could be used in human cells; (ii) evidenced that the skilled person willing to increase the specificity of Cas9 would have explored areas different from the use of cooperating nickases as in the claimed invention ("*Potential avenues for improving CRISPR specificity include evaluating Cas9 homologs identified through bioinformatics and directed evolution of these nucleases toward higher specificity*"; see page 3, lines 31 to 33); and (iii) was silent about the use of Cas9 nickases, except on page 3, noting that "*inactivating one of the Cas9 nuclease domains increases the ratio of HR to NHEJ and may reduce toxicity*" (see lines 35 to 37), but without suggesting any further use of such nickases. The appellant concluded from this that the disclosure in document D25 did not remedy the deficiencies of D2.

41. The board is not able to distil from these submissions an argument which would justify revising the board's conclusion in point 39.

42. During oral proceedings, the appellant has furthermore argued that the skilled person would not consider applying the CRISPR/Cas system tools disclosed in document D2 to primary T-cells (as defined in

paragraph [0044] of the patent), noting that document D25 only referred to cell lines.

43. It is established in the case law of the Boards of Appeal that in cases such as the one in hand, where the selection of primary T-cells merely amounts to an arbitrary selection from a number of equal alternatives of white blood cells and thus represents a mere obvious and consequently non-inventive selection among a number of known cell alternatives, the "could-would approach" normally does not apply (see e.g. decisions T 1968/08, T 12/07 and T 894/19). In fact, all known white blood cell alternatives are equally obvious solutions for the formulated objective technical problem, and it is sufficient that the skilled person recognise the solutions concerned without inventive effort; a particular pointer not being required for this purpose. As argued by the appellant, it was known that primary cells may be more suitable for use in therapy, so the skilled person would be motivated to use primary T-cells rather than white blood cell lines and be able to do so routinely.

Conclusion (inventive step of the main request)

44. In view of the above considerations, the subject-matter of claim 1 of the main request lacks an inventive step.

Appellant's request for stay of proceedings

45. Shortly before the date of oral proceedings, the appellant requested that the proceedings be stayed in view of an envisaged referral to the Enlarged Board of Appeal in appeal case T 439/22 should the amended description according to the main request not be

admitted into the proceedings (see sections IX. and XII.).

46. The appellant justified the request by arguing that the description of the main request contains an amended paragraph [0017] which was newly formulated in response to arguments of the respondent on the interpretation in the patent of the term "cleavage" based on paragraph [0017] of the granted version.

47. The board's above assessment of inventive step of the claimed subject-matter concurs with the respondent's submission that the subject-matter of claim 1 of the main request lacks an inventive step, but without having to recourse to the wording of paragraph [0017] of the description. Accordingly, the board saw no reason to consider and grant the appellant's request for a stay as formulated.

Auxiliary requests - admission

48. A number of auxiliary requests have been filed in appeal, and the respondent has requested that none be admitted. In view of the conclusions on a substantial procedural violation (see below), the board has not taken a decision on admission of any auxiliary request on file.

Substantial procedural violation - remittal to the opposition division for further prosecution

49. In the context of the admittance of the auxiliary requests filed with the grounds of appeal, the appellant argued that after the opposition division had announced at the oral proceedings that former auxiliary request 2, filed by the appellant during the oral

proceedings, did not fulfil the requirements of Article 123(2) EPC (and was not admitted into the proceedings), the opposition division "*arbitrarily refused that* [the appellant] *file*[d] *any other request to correct this deficiency, asserting that 'no solution of the problems would be recognizable and that no further requests would be allowed' (see point 49 of the minutes)*" (see statement of grounds of appeal, point IV.3.1). By refusing the submission of further requests, the opposition proceedings suffered from a substantial procedural violation by virtue of infringing the appellant's right to be heard (Article 113(1) EPC).

50. As can be seen from point 49 ("*P asked whether she was not allowed to file any further requests. CH confirmed that no further requests were allowed*") and also from point 58 of the minutes, the opposition division indeed refused the filing of any further amended auxiliary requests in advance, without having seen the amendments. Also, no reasons for the opposition division's refusal were given in the decision under appeal.

51. Refusing any further amendment without knowing the content of the amended auxiliary requests is, as a rule, an unreasonable way of exercising the discretion pursuant to Rule 116(2), fourth sentence, EPC and Article 114(2) EPC and constitutes a substantial procedural violation (see decision T 1758/15, Reasons 1.1.4). At the same time, by refusing the filing of further auxiliary requests, the appellant's right to be heard under Article 113(1) EPC was violated. Without knowing the content of the requests, it was impossible for the opposition division to assess whether the amendments were appropriate, i.e. a fair

attempt to overcome the objections, and whether the requests were *prima facie* allowable. Refusing any further amendment may be an appropriate approach only if it has become evident, after various unsuccessful amendment attempts, that the patent proprietor is not seriously trying to overcome the objections but is only delaying the proceedings (see decision T 1758/15, Reasons 1.1.5). In the case in hand, however, the discretionary decision not to admit any further auxiliary requests was taken without the opposition division having identified any signs of procedural abuse.

52. For this reason alone, the board agrees with the appellant that the opposition division, by refusing the submission of further requests at the end of the oral proceedings, violated the appellant's right to be heard and that, consequently, the opposition proceedings suffered from a substantial procedural violation.

53. The board is further of the opinion that additionally the opposition division failed to duly consider the following circumstances of the opposition proceedings when exercising its discretion not to admit any further auxiliary request into the proceedings.

- In the decision under appeal, the opposition division based its objection of lack of inventive step of the subject-matter of claim 1 of former auxiliary request 1 on the teaching of document D2 in combination with the teaching of D25 (see point 10. above).

- This objection was raised for the first time in a letter with third-party observations filed after the first summons to oral proceedings. In the

communication accompanying the first summons, the opposition division had expressed its preliminary opinion that the ground for opposition under Article 100(c) EPC prejudiced maintaining the patent as granted but that the grounds for opposition under Article 100(b) and (a) EPC, the latter in conjunction with Articles 54 and 56 EPC, did not.

- The appellant replied to the third-party observations and requested that they be disregarded. The third party replied to the appellant's reply in a second letter. The respondent also replied to the appellant's reply in two letters, requesting that the appellant's submissions be not admitted into the proceedings for being late filed and that the opposition division consider the third-party observations. In neither letter did the respondent comment on the substance of the third-party observations.

- After the first oral proceedings had been cancelled, the opposition division issued a new summons for a later date. In the communication accompanying the second summons, the opposition division mentioned the first letter with the third-party observations without commenting on their relevance. Nor did it mention the third party's second letter. The opposition division merely stated that it maintained its preliminary opinion provided in its first communication.

- The oral proceedings were cancelled for a second time. In the communication accompanying the third summons for oral proceedings, the opposition

division merely referred to its previous two communications.

- When asked by the opposition division during the oral proceedings to specify the closest prior art and apply the problem-solution approach for inventive step of the subject-matter of claim 1 of former auxiliary request 1, the respondent merely referred to the two letters with third-party observations and did not provide any further arguments (see point 29 of the minutes).

54. Although Article 114(2) EPC mentions only the parties to the proceedings, established case law holds that submissions (i.e. facts and evidence) emerging from third-party observations not filed until after expiry of the opposition period are likewise to be treated, by way of a legal fiction, as "late" (see CLBA, section III.N.4.4.1). Consequently, opposition divisions should at least comment on the relevance of third-party observations, for example in the summons to oral proceedings. If the opposition division considers the third-party observations to be relevant to the decision and wishes to take them up *ex officio* and consider them in the proceedings pursuant to Article 114(1) EPC, a decision on the admission of the third-party observations into the proceedings must first be taken at the discretion of the opposition division on the basis of their *prima facie* relevance (see decision T 1756/11, Reasons 2.5 and 2.7).

55. In the case in hand, the opposition division failed to comment on the relevance of the third-party observations in any of its communications, nor did it decide on their admission (see point 53.). Rather, the opposition division maintained its positive preliminary

assessment on inventive step even in the knowledge of the third-party observations. In view of these circumstances and also the fact that the respondent did not rely on the third-party observations in the written proceedings, the board agrees with the appellant that the course of the oral proceedings and the opposition division's change of mind must have come as a surprise to the appellant. The appellant was therefore entitled to react to the changed circumstances by filing new auxiliary requests to overcome the objection of lack of inventive step. For this reason too, therefore, the opposition division violated the appellant's right to be heard by refusing the filing of further auxiliary requests.

56. The board's conclusions in points 52. and 55. above are not altered by the fact, as invoked by the respondent, that according to point 51 of the minutes the appellant stated during the oral proceedings that it "*had no further requests*". Indeed, this statement - if accurate, see below - must be seen in the context of the preceding statement of the opposition division that "*no further requests would be allowed*" and the subsequent opposition division's confirmation of the refusal in response to the appellant's renewed enquiry (see points 49 and 58 of the minutes). Consequently, the appellant's statement that it had no further requests cannot be interpreted as meaning that it withdrew its request to file further auxiliary requests or that it waived its right to do so. Against this background, the appellant's request for correction of point 51 of the minutes (see letter dated 4 April 2022) and the opposition division's refusal of the correction request (see communication dated 22 April 2022) are of no relevance.

57. Moreover, the respondent claimed that a possible procedural violation on the part of the opposition division did not affect the whole proceedings. In fact, since none of the auxiliary requests filed by the appellant were allowable, the outcome would have been the same, i.e. the opposition division would still have taken the same decision to revoke the patent.

58. However, the board is not convinced by this argument. Indeed, it is speculative to hold that the appellant would have filed the same auxiliary requests during the oral proceedings before the opposition division as later done with its statement of grounds of appeal and whether the opposition division would then have actually revoked the patent. The board therefore does not need to examine whether the auxiliary requests filed by the appellant in the appeal proceedings are not allowable, as asserted by the respondent.

59. Lastly, the board notes that the decision under appeal omits to provide reasons for not having allowed the appellant to file further auxiliary requests during the oral proceedings. Also for this reason, the opposition proceedings suffered from a substantial procedural violation by virtue of infringing the appellant's right to be heard by not providing a proper reasoning (Rule 111(2) EPC in conjunction with Article 113(1) EPC).

60. Accordingly, due to the fundamental deficiencies in the first-instance proceedings described above, there are special reasons within the meaning of Article 11 RPBA in conjunction with Article 111(1), second sentence, EPC for remitting the case to the opposition division for further prosecution.

Reimbursement of the appeal fee

61. The reimbursement of the appeal fee in the event of a substantial procedural violation is governed by Rule 103 EPC. Under Rule 103(1)(a) EPC, the appeal fee must be reimbursed in full if the board deems an appeal to be allowable if reimbursement is equitable by reason of a substantial procedural violation.

62. By remitting the case to the opposition division for further prosecution (see point 60.), the board has thus decided to set aside the decision under appeal and allow the appeal.

63. The board considers that the substantial procedural violations referred to above had a causal link with the necessity for the appellant to file the appeal. Indeed, had the opposition division taken the appellant's comments and any newly filed requests into consideration, its final decision might have been different.

64. In view of the above considerations, the board held it equitable to order the reimbursement of the appeal fee in accordance with Rule 103(1)(a) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

3. The appeal fee is reimbursed.

The Registrar: The Chair:

A. Vottner T. Sommerfeld

Decision electronically authenticated