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**Datasheet for the decision
of 7 March 2024**

Case Number: T 0521/18 - 3.3.08

Application Number: 12183074.9

Publication Number: 2532745

IPC: C12N15/10, C12Q1/68, C07H21/04

Language of the proceedings: EN

Title of invention:
Method and Compositions for Detection and Enumeration of
Genetic Variations

Patent Proprietor:
The Johns Hopkins University

Opponents:
Roche Diagnostics GmbH
Grund, Martin, Dr.

Headword:
A liquid composition/The Johns Hopkins University

Relevant legal provisions:
EPC Art. 54, 88(1), 123(2)
RPBA Art. 12(4)

Keyword:

Main request - novelty - (no)

Auxiliary request 1- added subject-matter - (yes)

Auxiliary requests 2 to 4 - admittance/consideration - (no)

Decisions cited:

G 0001/22, G 0002/22, G 0003/14



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Case Number: T 0521/18 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 7 March 2024

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 13 December
2017 revoking European patent No. 2532745
pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	M. Montrone
	A. Bacchin
	R. Morawetz
	R. Winkelhofer

Summary of Facts and Submissions

- I. The appeal of the patent proprietor ("appellant") lies from the decision of an opposition division to revoke the European patent No. 2 532 745. This patent is based on European patent application No. 12 183 074.9 (the "patent application"), which is a divisional application of the earlier European patent application No. 04 752 581.1 published as International patent application WO 2005/010145.

- II. Two oppositions were filed against the patent. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC in relation to novelty (Article 54 EPC) and Article 100(b) and (c) EPC. The opposition division held that the main request and auxiliary requests 1, 2, 5 and 6 did not comply with Articles 123(2) and 76(1) EPC. Further, the opposition division held that auxiliary requests 3 and 4 complied with Articles 123(2)/76(1), 84 and 83 EPC, but lacked novelty (Article 54(3) EPC) over the disclosure of document D4 which was held to be entitled to priority from US 60/476,504 (document D4a, application "P4" dated 6 June 2003).

- III. With their statement of grounds of appeal, the appellant submitted a main request (corresponding to auxiliary request 3 dealt with in the decision under appeal) and auxiliary requests 1 to 4. While auxiliary request 1 corresponds to auxiliary request 2 dealt with in the decision under appeal, auxiliary requests 2 to 4 are new to the proceedings. In support of the appellant's case, new evidence was submitted (documents D12 to D17).

IV. Claim 1 of the main request reads:

"1. A liquid composition comprising a plurality of microemulsions forming aqueous compartments wherein at least a portion of said aqueous compartments comprise:
a bead;
a DNA template; and
oligonucleotide primers for amplifying said DNA template;
wherein at least a portion of the oligonucleotide primers is bound to the bead and the DNA template is not bound to the bead."

V. Claim 1 of auxiliary request 1 reads:

"1. A liquid composition comprising a plurality of microemulsions forming aqueous compartments wherein at least a portion of said aqueous compartments comprise:
a bead;
a polynucleotide template; and
oligonucleotide primers for amplifying said template;
wherein at least a portion of the oligonucleotide primers is bound to the bead and remain stably bound during polymerase chain reaction amplification."

VI. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "*and wherein the polynucleotide templates in the plurality of aqueous compartments differ by a feature selected from the group consisting of a single nucleotide polymorphism (SNP), by the presence or absence of a mutation, by the presence or absence of an insertion or deletion, and the presence or absence of a non-single nucleotide polymorphism*" has been added.

- VII. Claims 1 of auxiliary requests 3 and 4 differ from claim 1 of auxiliary request 1 in that the feature "*remain stably bound during polymerase chain reaction amplification*" is replaced by "*wherein binding of said oligonucleotide primers to said bead is via a biotin-streptavidin binding pair, wherein said forward or reverse oligonucleotide primers that are bound to said bead comprise at least two biotin groups*".
- VIII. In reply, both opponents ("respondents I and II") submitted *inter alia* additional evidence (documents D18 and D19).
- IX. In a further response, the appellant submitted, *inter alia*, as regards auxiliary request 2: "*The typographical error in the claim related to polynucleotide templates has been corrected. It is clear that this is what was intended in view of the amendments to "DNA template", and this correction should not prejudice its admissibility into the proceedings. This correction is enclosed as new Auxiliary Request 2 to replace the Auxiliary Request 2 currently on file*".
- X. In a communication pursuant to Article 15(1) RPBA, the board provided its preliminary assessment according to which none of the sets of claims on file seemed allowable or admissible. Moreover, it was underlined that, contrary to the appellant's statement (see previous section), a corrected auxiliary request 2 had, in fact, not been submitted.
- XI. Respondent I and the appellant withdrew their requests for oral proceedings.
- XII. The board cancelled the scheduled oral proceedings.

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

D4: WO 2004/069849

D4a: US 60/476,504 ("P4" priority application of document D4)

D10: Declaration of John H. Leamon, dated 27 June 2017

D11: Declaration of Gary J. Sarkis, dated 30 October 2017

D12: LinkedIn profile of Jan Berka

D13: LinkedIn profile of Yi-Ju Chen

D14: LinkedIn profile of Vinod Makhijani

D15: Schlecht U. *et al.*, Scientific Reports, 2017, Vol. 7, 5252, 1-10

D16: WO 2017/210469

D17: WO 2017/013170

D18: Declaration of Vinod Makhijani, dated 4 September 2018

D19: US 60/443,471 ("P1" priority application of document D4).

XIV. The parties' submissions, insofar as relevant to the present decision, are dealt with in the Reasons part of this decision.

- XV. The appellant requests:
- that the decision under appeal be set aside and amended such that the patent be maintained on the basis of the main request, or in the alternative, on the basis of auxiliary requests 1 to 4, all submitted with the grounds of appeal,
 - that documents D18 and D19 not be admitted into the proceedings.

- XVI. Both respondents request:
- that the appeal be dismissed,
 - that auxiliary requests 2 to 4 not be admitted into the proceedings.

(a) Respondent I further requests:

- that auxiliary request 1 not be admitted, and
- that the case be remitted to the first instance should auxiliary requests 3 and/or 4 be admitted.

(b) Respondent II further requests:

- that documents D12 to D14 not be admitted into the proceedings.

Reasons for the Decision

Main request

Novelty

1. The opposition division held that document D4 which was filed in the name of 454 Corporation (designated for the States outside the US) and 10 inventors/applicants (designated for the US only), was entitled to priority from application P4 (D4a), which

had been filed in the name of 7 inventors/applicants out of the 10 inventors/applicants of document D4 (see decision under appeal, points 21.1 to 21.7).

Furthermore, the opposition division held that the subject-matter of claims 1 and 5 of auxiliary request 3 (now main request) lacked novelty over the disclosure of document D4 (see decision under appeal, points 22.1 to 22.3).

2. The board agrees with these findings with regard to both the priority entitlement of document D4 and the lack of novelty of claims 1 and 5 of the present main request.
- 2.1 As regards the question of priority entitlement of document D4, decisions G 1/22 and G 2/22 have set out that under the EPC normally a strong presumption exists that the priority applicants accept the subsequent applicant's reliance on the priority right for the purposes of Article 88(1) EPC (see Reasons 105 to 107). This strong presumption also applies in a situation where a PCT application is jointly filed by parties A and B, (i) designating party A for one or more designated States and party B for one or more other designated States, and (ii) claiming priority from an earlier patent application designating party A as the applicant. The joint filing implies an agreement between parties A and B allowing party B to rely on the priority, unless there are substantial factual indications to the contrary (see Order II. of G 1/22 and G 2/22).
- 2.2 This strong presumption applies in the present case, which corresponds to the situation referred to in Order II. of G 1/22 and G 2/22.

- 2.3 Such a presumption can only be rebutted in the presence of "serious" doubts based on facts or clear indications to the contrary (see G 1/22 and G 2/22, Reasons 110 and 125). The appellant filed documents D12 to D14 to cast doubts that a valid priority transfer took place from the inventors to 454 Corporation.
- 2.4 However, documents D12 to D14 do not cast any such doubts on the presumption of an assignment. These documents are LinkedIn profiles of three further inventors (Jan Berka, Yi-Ju Chen and Vinod Makhijani) of application P4 (D4a) that show that they are employed by Roche, i.e. the company that bought 454 Corporation in 2007. Documents D12 to D14 are irrelevant to the question whether there was an agreement between the parties named as applicant in P4 (D4a) and those named as applicant in document D4, allowing the latter to rely on the priority right established by the filing of P4 (D4a). In particular documents D12 to D14 contain no evidence concerning a transfer of rights, be it in favour or against it. Nor do these documents provide evidence that Roche as their employer has access to employment contracts previously signed with a different company, i.e. 454 Corporation. The same considerations are valid for the further publications indicating that some of the present inventors were employed by Roche at a much later point in time, namely in 2017 (see documents D15 to D17).
- 2.5 The evidence based on documents D12 to D14 and D15 to D17 therefore raises speculative doubts on unspecific facts only. This evidence is not suitable to rebut the strong presumption on entitlement as also confirmed by the declarations of two inventors of document D4, Mr Leamon (see document D10, point 5) and Mr Sarkis (see document D11, point 5).

- 2.6 For these reasons, and with regard to respondent II's request of non-admittance, there is no need to consider documents D12 to D14 in these appeal proceedings.
- 2.7 Further, the appellant requested not to admit/consider documents D18 and D19 in these appeal proceedings. The board sees likewise no need to consider document D18 (a further inventor declaration of document D4), and document D19, the first priority application ("P1") of document D4 apparently showing that 454 Corporation was an assignee of the right. Both documents would at most support a presumption of entitlement of priority, for which there is no doubt in the present case.
3. Consequently document D4 is entitled to priority from application P4 (D4a) and thus forms prior art for the patent at least according to Article 54(3) EPC.
4. In view of the board's conclusion on document D4's valid priority, respondent II's objection to the validity of the priority claimed by the patent in suit (see reply, points 6.15 to 6.17) needs not be addressed.
5. The appellant has not provided any substantiation that the opposition division's finding was erroneous that the subject-matter of claims 1 and 5 of the main request (then auxiliary request 3) lacked novelty over the disclosure of document D4 if this document is entitled to priority from application P4 (D4a). The board has therefore no reason to depart from the opposition division's decision on this issue.
6. The main request contravenes Article 54 EPC.

Auxiliary request 1

Admittance/consideration of auxiliary request 1

7. Respondent I requested that auxiliary request 1 not be admitted into the proceedings since the subject-matter of claim 1 was broader than that of the main request.
8. Auxiliary request 1 has been dealt with in the decision under appeal as auxiliary request 2. Already for this reason, auxiliary request 1 has to be considered in the appeal proceedings (Article 12(1)(a) RPBA).

Added subject-matter

9. In the following reference to the application as filed is to the patent application as published (EP 2 532 745 A2).
10. The opposition division held that the feature "*the oligonucleotide primers... remain stably bound during polymerase chain reaction amplification*" in claim 1 of auxiliary request 2 (now auxiliary request 1) comprised added subject-matter. The application as filed was silent on an "*unambiguous generic disclosure of primers that remain stably bound during polymerase chain reaction amplification, in particular when no streptavidin-beads are used*". Claim 1 thus formed "*an unallowable generalisation*" from the application as filed (see decision under appeal, points 17.1 to 17.3).
11. The contested feature in claim 1 relates to at least a portion of primers that is bound to beads. This primer binding is further functionally characterised by a result to be achieved, namely that the primers "*remain*

stably bound during polymerase chain reaction amplification".

- 11.1 Claim 1 is silent on any means to achieve these results and thus is not limited to a streptavidin-biotin coupling of primers to beads but encompasses all forms of primer/bead binding that might be suitable for this purpose.
- 11.2 Further as regards the stability of this binding, the functional requirement "*during polymerase chain reaction amplification*" implies that the binding should be suitable to last at least for the time period and under the conditions of PCR amplification reactions.
12. The appellant submitted that basis for the contested amendment in claim 1 could be found "*throughout the application as filed and in particular in paragraphs 15, 51 and Figure 1*". Further, paragraphs [0025] and [0033] of the application as filed were indicated as basis (see statement of grounds of appeal, page 7, fifth and tenth paragraph).
13. The board agrees with the opposition division that the disclosure of paragraphs [0015] and [0051] of the application as filed (see page 3, lines 23 and 24 and page 8, lines 13 to 16) as well as Figure 1 is limited to a streptavidin-biotin coupling of oligonucleotides to beads during a PCR amplification which cannot be generalised to any binding suitable for PCR amplification.
- 13.1 Paragraph [0025] of the application as filed discloses modified beads, including *inter alia* streptavidin-biotin. However, said paragraph is silent on any primers bound to beads, let alone by any of the

disclosed modifications, or that the use of these modifications is suitable for keeping primers stably bound to beads during PCR amplification. This is also not implicitly disclosed.

- 13.2 Paragraph [0033] of the application as filed discloses that "*Oligonucleotide primers can be bound to beads by any means known in the art. They can be bound covalently or non-covalently. They can be bound via an intermediary, such as via a protein-protein interaction, such as an antibody-antigen interaction or a biotin-avidin interaction. Other specific binding pairs as are known in the art can be used as well*". Like paragraph [0025], this paragraph does not mention that primers "*remain stably bound*" to beads during PCR amplification. Furthermore the disclosure of "*bound to beads by any means known in the art*" or "*via an intermediary*" in paragraph [0033] does not necessarily result in primers that remain stably bound to beads during PCR amplification under all conditions applied. Paragraph [0033] therefore does not implicitly disclose this functional requirement of claim 1 either.

14. Claim 1 of auxiliary request 1 therefore does not comply with the requirements of Article 123(2) EPC.

Admittance/consideration of auxiliary requests 2 to 4

15. Auxiliary requests 2 to 4 have been submitted by the appellant for the first time with their statement of grounds of appeal. These sets of claims are thus new to the proceedings.
16. According to the case law established by the Boards of Appeal, the function of an appeal is to give a judicial decision upon the correctness of a separate earlier

decision taken by an examining or opposition division. Appeal proceedings are not an opportunity to re-run or re-open proceedings before any of these divisions. The admittance (consideration) of *inter alia* new requests into the appeal proceedings is at the board's discretion (Article 12(4) 2007 RPBA). The principal criterion applied for admittance under Article 12(4) RPBA 2007 is whether or not the patent proprietor (appellant) could have filed these requests earlier, i.e. during the first instance proceedings. A further criterion is whether or not a request *prima facie* gives rise to new issues or objections.

17. As regards auxiliary request 2, the appellant submitted that this request "*largely*" corresponded to auxiliary request 4 dealt with in the decision under appeal which had been submitted at the oral proceedings before the opposition division (see statement of grounds of appeal, page 8, first paragraph and minutes of the oral proceedings, point 13). Furthermore, the appellant submitted that auxiliary request 2 could not have been submitted earlier because an amendment introduced in claim 1 of this set of claims in parallel but later proceedings concerning the parent patent was held by the opposition division as sufficient to reinstate novelty over document D4. Also the use of "*polynucleotide templates*" instead of "*DNA templates*" in claim 1 was an error which should not prejudice auxiliary request 2's admittance into the proceedings (see submission of 28 October 2019, page 4, fourth and fifth paragraphs).
- 17.1 Both respondents submitted that auxiliary request 2 was submitted late and that this request caused new issues.

- 17.2 As indicated above, the appellant - although stating differently (see section IX, above) - has not submitted a corrected auxiliary request 2. Accordingly, auxiliary request 2 on file due to the presence of the term "*polynucleotide templates*" in claim 1 is unclear (Article 84 EPC) because the term lacks an antecedent basis in claim 1, as indicated by the respondents (see respondent I's reply, point 4.2.4(b), and respondent II's reply, point 7.5). Furthermore, the board agrees with respondent I (see reply, point 4.2.4(d)) that the "*absence of a mutation*" as an embodiment of claim 1 does not result in polynucleotide templates which differ from each other - contrary to the wording of the claim. Also for this reason, claim 1 of auxiliary request 2 lacks *prima facie* clarity (Article 84 EPC).
- 17.3 Since the amendments in claim 1 introduce *prima facie* new clarity issues (Article 84 EPC), auxiliary request 2 could not be considered/admitted into the proceedings.
18. As regards auxiliary requests 3 and 4, the appellant submitted that these requests "*largely*" corresponded to auxiliary request 5 dealt with in the decision under appeal (see statement of grounds of appeal, page 8, seventh paragraph, in relation to auxiliary request 3). The amendment ("*forward or reverse*") introduced in claims 1, 5 and 10 of auxiliary request 3 and in claim 1 of auxiliary request 4 was derived from dependent claim 3 part (13) as granted. As basis for said amendment, clauses 32 and 33 of the application as filed were indicated (see paragraph [0069]). Moreover, the appellant submitted that these requests could not have been submitted earlier since they directly addressed the opposition division's refusal (see

submission dated 28 October 2019, page 4, ninth paragraph).

- 18.1 Both respondents submitted that auxiliary requests 3 and 4 should not be admitted into the proceedings because of their late filing. Respondent I argued in this context that the omission of "*forward or reverse*" primers from claim 1 of auxiliary request 5 had been discussed during the oral proceedings before the opposition division, but that the appellant had refrained from submitting an amended request (see reply, point 5.2.2 and minutes of the oral proceedings, point 19). Respondent II further submitted that amended claim 1 of auxiliary requests 3 and 4 caused new objections under lack of clarity (see reply, points 7.11 and 7.12).
- 18.2 As regards respondent II's submission that the term "*said forward or reverse oligonucleotide primers*" in claims 1 of auxiliary requests 3 and 4 was unclear because claim 1 lacked an antecedent for these primers the following is relevant. It is established case law that an amendment resulting from the combination of subject-matter of an independent and a dependent claim as granted (here: of granted claims 1 and 3 part (13)) is not open to an objection under Article 84 EPC (see G 3/14, Reasons 80 and 81).
- 18.3 As regards the question whether or not auxiliary requests 3 and 4 could have been filed earlier, the course of events during the opposition proceedings is relevant.
- 18.4 Auxiliary request 5 dealt with in the decision under appeal (from which in essence new auxiliary requests 3 and 4 are derived) had been submitted by the appellant

as third auxiliary request in reply to the respondents' notices of opposition.

18.5 The opposition division has not commented in the communication setting out its preliminary opinion annexed to the summons on substantial issues of any of the auxiliary requests filed in reply to the notices of opposition. Nor did the respondents submit any objections against these requests in their replies to the summons.

18.6 At the oral proceedings before the opposition division, the opposition division concluded that claims 1, 5 and 10 of auxiliary request 5 comprised added subject-matter (see decision under appeal, point 27.3).

19. It is evident from this course of events that the discussion on added subject-matter of auxiliary request 5 took place for the first time at the oral proceedings before the opposition division. The introduction of the objected terms "*forward or reverse*" into claims 1, 5 and 10 of present auxiliary request 3 or into claim 1 of present auxiliary request 4 is straightforward to overcome the opposition division's objection. The amendment simply adds the feature missing from claim 1 of auxiliary request 5 dealt with in the decision under appeal (see decision under appeal, point 27.3) by introducing the literal wording of claim 3 part (13) as granted.

19.1 However, since the amendment in auxiliary requests 3 and 4 is so straightforward, in particular in light of the opposition division's invitation of the parties to comment on the existence of other primers than reverse or forward ones (see minutes of the oral proceedings, point 19), the question arises why the appellant could

not have submitted amended auxiliary requests 3 and 4 at the oral proceedings before the opposition division.

19.2 In reply to the communication under Article 15(1) RPBA, the appellant has not challenged the board's preliminary assessment that auxiliary requests 3 and 4 could have been submitted earlier. The board thus has no reason to deviate from its preliminary assessment.

19.3 Accordingly, auxiliary requests 3 and 4 cannot be admitted into the appeal proceedings either.

20. In the absence of any valid claim requests, the appeal is not allowable, for the reasons given.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



L. Malécot-Grob

T. Sommerfeld

Decision electronically authenticated