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# Datasheet for the decision of 2 July 2024

**Case Number:** T 1332/22 - 3.3.08

**Application Number:** 16195596.8

**Publication Number:** 3150722

**IPC:** C12Q1/6844

**Language of the proceedings:** EN

**Title of invention:**
Production of closed linear DNA

**Patent Proprietor:**
Touchlight IP Limited

**Opponent:**
ZBM PATENTS, S.L.

**Headword:**
*In vitro* cell-free production of closed linear DNA/TOUCHLIGHT

**Relevant legal provisions:**
EPC Art. 76(1)

**Keyword:**
Divisional application - added subject-matter (yes)

**Decisions cited:**
G 0009/92, G 0001/05, G 0002/10, T 0169/93

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**Case Number: T 1332/22 - 3.3.08**

# D E C I S I O N
# of Technical Board of Appeal 3.3.08
# of 2 July 2024

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Touchlight IP Limited<br>40 Queen Anne Street<br>London<br>W1G 9EL (GB) |
| **Representative:** | Cooley (UK) LLP<br>22 Bishopsgate<br>London EC2N 4BQ (GB) |
| **Respondent:** (Opponent) | ZBM PATENTS, S.L.<br>Rambla Catalunya, 123<br>08008 Barcelona (ES) |
| **Representative:** | ZBM Patents - Zea, Barlocci & Markvardsen<br>Rambla Catalunya, 123<br>08008 Barcelona (ES) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 17 March 2022 revoking European patent No. 3150722 pursuant to Article 101(3)(b) EPC** |

**Composition of the Board:**

| | |
|---|---|
| **Chairwoman** | T. Sommerfeld |
| **Members:** | R. Morawetz |
| | A. Bacchin |

## Summary of Facts and Submissions

I. European patent No. 3 150 722 ("the patent") is based on European patent application No. 16 195 596.8, which was filed as a divisional application in respect of earlier (parent) European patent application No. 13 152 077.7. The latter had been filed as a divisional application in respect of earlier (grandparent) European patent application No. 10 702 726.0 filed as an international application and published as WO 2010/086626.

II. An opposition was filed against the patent as granted. The patent was opposed in its entirety under Article 100(a) EPC on the ground of lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.

III. The opposition division revoked the patent. It held, *inter alia*, that the subject-matter of claims 1 to 5 of the main request filed by letter dated 20 January 2022 met the requirements of Article 76(1) EPC but that claims 1 and 3 of the main request contravened Article 56 EPC.

IV. The patent proprietor (appellant) appealed against the opposition division's decision.

V. With its statement setting out the grounds of appeal, the appellant maintained the set of claims of the main request considered in the decision under appeal as its main request and submitted sets of claims of new auxiliary requests I to IV.

The two independent claims of the main request, claims 1 and 3, read as follows:

"1. A process for *in vitro* cell-free production of closed linear DNA comprising:
- amplifying DNA from a DNA template comprising more than one protelomerase target sequence using a strand displacement DNA polymerase, and
- contacting said amplified DNA with at least one protelomerase under conditions promoting production of closed linear DNA.

3. Cell-free, *in vitro* double stranded concatameric DNA comprising multiple repeats of a DNA sequence, wherein said repeat DNA sequences are separated by a protelomerase target sequence."

Claim 3 of each of auxiliary requests I to IV is identical to claim 3 of the main request.

VI. In its reply to the statement of grounds of appeal, the opponent (respondent) argued that, contrary to the opposition division's decision, claims 1 to 5 of the main request related to added subject-matter.

VII. In response, by letter dated 16 May 2023, the appellant submitted that the principle of *reformatio in peius* applied and that the opposition division had rightly concluded that claims 1 to 5 of the main request complied with the requirements of Article 76 EPC. The appellant also submitted new auxiliary requests V to IX.

VIII. The board scheduled oral proceedings, in accordance with the parties' requests, and issued a communication under Article 15(1) RPBA. At oral proceedings, the

appellant withdrew auxiliary requests V to IX.

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

X. The parties' final requests relevant for this decision were as follows.

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the set of claims of the main request filed by letter dated 20 January 2022, or on the basis of one of the sets of claims of auxiliary requests I to IV filed with the grounds of appeal. In the event that the decision under appeal was upheld for any of the claims of the main request in relation to added subject-matter, the appellant requested that it be permitted to delete the other claims.

XI. The respondent (opponent) requested that the appeal be dismissed and that auxiliary requests I to IV not be admitted into the proceedings.

## Reasons for the Decision

*Main request*

*Added subject-matter (Article 76(1) EPC)*

1. The appellant submits that the principle of the prohibition of *reformatio in peius* applies (cf. letter dated 16 May 2023, point 3.2) and that therefore the respondent's objections of added matter against the claims of the main request cannot be considered in the appeal proceedings.

2. Contrary to the appellant's arguments, the principle of prohibition of *reformatio in peius* does not apply to the case in hand. In accordance with decision G 9/92 of the Enlarged Board of Appeal (OJ EPO 1994, 875), the principle of prohibition of *reformatio in peius* applies if the patent proprietor is the sole appellant against an interlocutory decision maintaining a patent in amended form (Headnote I). However, it does not apply if the patent proprietor appeals against a decision revoking a patent, as in this appeal. In the circumstances of the case in hand, the respondent may therefore re-argue issues that were already raised before the opposition division, i.e. added matter, and the board may review the opposition division's decision on all requirements of the EPC, including those that the opposition division considered to be met, such as Article 76(1) EPC (see also Case Law of the Boards of Appeal, 10th edition, 2022, "Case Law", V.A.3.1.1, V.A.3.1.6 and T 169/93, Reasons 2.1 to 2.6).

3. The standard for assessing compliance with the requirements of Articles 123(2) and 76(1) EPC is the same (see G 1/05, OJ EPO 2008, 271, Reasons 5.1), namely the standard set out in decision G 2/10 (OJ EPO 2012, 376, Reasons 4.3), also known as the "gold standard". Amendments are only permitted within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the earlier application as filed. After the amendment, the skilled person may not be presented with new technical information (ibid., Reasons 4.5.1).

4. It is well established in the case law of the boards of appeal that the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments of the application can be combined in order to artificially create a particular embodiment. In the absence of any pointer to the claimed combination of features, the combined selection of features cannot be clearly and unambiguously derived from the content of the application as filed for the person skilled in the art (Case Law, II.E.1.6.1(a)).

5. Reference is made below to the page and line numbering of the grandparent application WO 2010/086626, referred to as the "application".

*Claim 1*

6. Claim 1 of the main request relates to a process for *in vitro* cell-free production of closed linear DNA, comprising amplifying DNA from a DNA template, the DNA template comprising more than one protelomerase target sequence (see section V. above for the complete wording of the claim).

7. The opposition division held that the claim had a basis in the application as filed when starting from page 8, lines 13 to 16 combined with the disclosure on page 15, third paragraph and page 19, second paragraph of the application (decision under appeal, Reasons 39 to 49). In particular, the opposition division held that the disclosure on page 8, lines 13 to 16 of the application already implied the presence of at least one protelomerase target sequence, while page 15, third paragraph explained in more detail the role and structure of a protelomerase target sequence,

disclosing the feature "*more than one protelomerase target sequence*" recited in claim 1. Figures 1 and 4 were held to bring together the features of the claim.

8. For the following reasons, the board agrees with the respondent that the decision under appeal is incorrect on this point.

9. The application discloses that "[t]*he present invention provides an in vitro cell-free process for production of closed linear DNA molecules that comprises template-directed DNA amplification, and specific processing of amplified DNA by protelomerase*" (page 8, lines 13 to 16). The board agrees with the respondent that the feature "*and specific processing of amplified DNA by protelomerase*" merely implies that the amplified DNA contains at least one protelomerase target sequence. This, however, does not necessarily imply that the DNA template comprises a protelomerase target sequence.

10. Indeed, the application discloses (Figures 1 and 4) an amplified DNA containing a protelomerase target site (RL) which is obtained from a DNA template comprising only the right (R) and left arms (L) of the protelomerase binding sequence. These arms are physically separated and therefore do not form a complete protelomerase target sequence, which is defined on page 11, lines 29 to 31 of the application as a "*DNA sequence whose presence in a DNA template allows for its conversion into a closed linear DNA by the enzymatic activity of protelomerase*".

11. Therefore, the premise of the opposition division's reasoning that the disclosure on page 15, lines 13 to 16 of the application can be combined with the disclosure on page 8, lines 13 to 16 of the application

does not hold.

12. Furthermore, since the DNA templates disclosed in Figures 1 and 4 of the application do not comprise any protelomerase target sequence (point 10. above), they cannot serve as a pointer to combine the features relating to the presence of more than one protelomerase target sequence in the DNA template and displacement amplification either, contrary to what was held in the decision under appeal.

13. As its main line of argument, the appellant submitted that claim 1 was not directed to an undisclosed combination of features because the application explained the role and structure of the protelomerase target sequence on page 11, last paragraph, providing a verbatim basis for the feature "*comprising more than one protelomerase target sequence*" on page 15, third paragraph, which also explained why using more than one protelomerase target sequence in the DNA template was relevant and potentially desirable.

14. The passage on page 15, third paragraph of the application discloses that "[t]*he DNA template may comprise more than one protelomerase target sequence*" (emphasis added, page 15, lines 18 to 19). It explains that it is desirable to use multiple protelomerase target sequences when the DNA template contains short sequences of interest within a larger DNA molecule because this allows for "*excision of each short sequence of interest from the amplified DNA as a closed linear DNA, subject to the action of protelomerase (as shown in Figure 5)*" (page 15, lines 24 to 26).

15. In the board's judgement, the skilled person would therefore derive directly and unambiguously from the passage on page 15, third paragraph of the application that the feature "*more than one protelomerase target sequence*" is not generally applicable to all embodiments. Moreover, the passage on page 15, third paragraph provides no incentive to combine the disclosure of "*more than one protelomerase target sequence*" with the disclosure on page 8, lines 15 to 16 of the application, which does not relate to an embodiment in which the DNA template contains short sequences of interest within a larger DNA molecule, let alone an embodiment in which the DNA template necessarily comprises even one protelomerase target sequence (points 9. and 10. above).

16. In a further line of argument, made during oral proceedings before the board, the appellant submitted that page 8, lines 13 to 16 of the application provided the framework of claim 1 and disclosed most of its features, while page 11, lines 27 to 28 of the application defined the template and disclosed directly and unambiguously that there were only two options for the protelomerase target sequences, i.e. "one" or "more than one". It also submitted that page 15, line 18 of the application provided a verbatim basis for the feature "*more than one protelomerase target sequence*", teaching that this option allowed shorter sequences of interest to be excised from a larger DNA molecule. The skilled person faced with the two options disclosed on page 11, lines 27 to 28 of the application would therefore know when to choose the option "*more than one protelomerase target sequence*", so that no selection would be required. In addition, page 17, lines 5 to 6 of the application disclosed amplification of the DNA template while page 19, line 8 and page 27, line 5 of

the application disclosed that strand displacement-type polymerases were preferred. Since pages 8 to 27 of the application related to the same embodiment, only two choices had to be made.

17. For the following reasons, this line of argument is not found persuasive either.

18. First, the passage on page 8, lines 13 to 16 fails to disclose that the DNA template comprises any protelomerase target sequence (points 9. and 10. above). Nor does it disclose the use of a strand-displacement DNA polymerase.

19. Second, the passage on page 11, lines 27 to 29 of the application discloses that "[a]*ccording to the present invention, closed linear DNA molecules are generated by the action of protelomerase on DNA amplified from a DNA template comprising at least one protelomerase target sequence*".

20. In the board's judgement, the disclosure of "at least one" conceptually also encompasses, in addition to the options "one" and "more than one", the options "two", "three", "four", "five", etc. This is confirmed on page 15, lines 18 to 20 of the application. Therefore, the board cannot concur with the appellant that the expression "*at least one protelomerase target sequence*" directly and unambiguously discloses only two options.

21. Contrary to the appellant's assertion, pages 8 to 27 of the application do not relate to one and the same embodiment either. Thus, page 8, lines 13 to 16 of the application is silent about shorter sequences of interest or larger DNA molecules and discloses an embodiment in which the DNA template does not

necessarily comprise any protelomerase target sequence (point 9. above), while page 15 relates to embodiments in which "*the DNA template may comprise one or more sequences of interest (preferably expression cassettes) flanked on either side by protelomerase target sequences*" (page 15, lines 26 to 28 and Figure 5). Even if the board were to accept the appellant's interpretation of the expression "*at least one protelomerase target sequence*", the board considers that page 15 of the application does not provide any motivation to combine that option with the embodiment on page 8, lines 13 to 16, for the reasons already set out in point 15. above.

22. In sum, the board concludes from the above considerations that, absent any pointer in the application as a whole to the claimed combination of features, the subject-matter of claim 1, which results from the combination of the feature "*more than one protelomerase target sequence*" (not originally disclosed as a preferred – nor otherwise generally applicable – feature) with the embodiment disclosed on page 8, lines 13 to 16 of the application, presents the skilled person with new technical information which they cannot directly and unambiguously derive from the application as filed. In these circumstances, it is irrelevant that the application discloses that strand displacement-type polymerases are preferred.

23. The subject-matter of claim 1 extends beyond the content of the grandparent application as filed and the claim contravenes Article 76(1) EPC.

*Claim 3*

24. Claim 3 is for a cell-free, *in vitro* double-stranded concatameric DNA comprising multiple repeats of a DNA sequence, with said repeat DNA sequences being separated by a protelomerase target sequence.

25. The opposition division held that the claim had a basis in the application as filed in Figures 1 and 4 and the paragraph bridging pages 3 and 4 (decision under appeal, Reasons 58). In particular, the opposition division held that "the skilled person understands that the teaching of Fig. 4 to represent [sic] a general teaching which may be exemplified and reduced to practice with TelN protelomerase and TelN protelomerase target sequences" (ibid., Reasons 61) and that the skilled person derives from Figure 4F "the essential technical features of the intermediary product as specified in claim 3 of the MR" (ibid., Reasons 73).

26. For the following reasons, the board agrees with the respondent that the decision under appeal is incorrect on this point too, and that claim 3 relates to an unallowable generalisation of the disclosure of the paragraph bridging pages 3 and 4 of the application and Figures 1 and 4.

27. First, regarding the opposition division's "essential technical features" argument, the board notes that the test for compliance with Article 76(1) EPC is the standard set out in point 3. above, that the so-called essentiality test cannot take the place of that standard, and that in the more recent, and now well-established, case law of the boards of appeal, the essentiality test is no longer considered appropriate

(Case Law, II.E.1.4.4(c)).

28. Second, the disclosure in relation to Figure 4 of the application is explained in the paragraph bridging pages 3 and 4 of the application, as follows: "*Figure 4: Specific process for in vitro amplification of a linear double stranded covalently closed DNA using an RCA strand displacement DNA polymerase in combination with TelN protelomerase. A. Closed linear DNA template. R and L represent the DNA sequences of the right and left arms of the TelN protelomerase binding sequence. B. Denaturation of starting template to form circular single stranded DNA. C. Primer binding. D-E. Rolling circle amplification from single stranded DNA template by an RCA strand displacement DNA polymerase. F. Formation of long concatemeric double stranded DNA comprising single units of amplified template separated by protelomerase binding sequences (RL). G. Contacting with TelN protelomerase specific to RL sequence. Protelomerase cleaves concatameric DNA at RL site and ligates complementary strands to produce amplified copies of the original linear covalently closed DNA template.*"

29. The board agrees with the respondent that the opposition division's understanding that the expression "*Specific process*" referred only to the starting material of the process (decision under appeal, Reasons 59) is incorrect. The paragraph bridging pages 3 and 4 of the application and Figure 4 of the application disclose a particular embodiment starting from a specific template and resulting in a concatemer that contains no sequence other than a continuous repetition of that template.

30. Third, the board therefore also agrees with the respondent that Figure 4 and the paragraph bridging pages 3 and 4 of the application provide no basis for concatemers of any size, as encompassed by claim 3, and that the phrase "*comprising multiple repeats of a DNA sequence*" has no basis in Figure 4.

31. Fourth, in particular, the board agrees with the respondent that the opposition division erred in holding that the open-ended term "comprising" in claim 3 could justify a generalisation of the product disclosed in Figure 4 of the application (decision under appeal, Reasons 65 to 68).

32. The question to be considered when assessing whether the requirements of Article 76(1) EPC are met is not whether the wording of claim 3 of the main request encompasses the embodiment represented in Figure 4 of the application but whether the subject-matter of claim 3 of the main request has a basis in the embodiment represented in Figure 4 of the application.

33. The appellant submitted that in addition to Figure 4 of the application, page 27, lines 5 to 21 of the application in combination with page 28, lines 6 to 7 disclosed all the subject-matter of claim 3.

34. For the following reasons, this line of argument is not found persuasive either.

35. First, the application discloses that "[a]*s discussed above, long linear single stranded DNA molecules are initially formed in strand displacement reactions which then serve as new templates, such that double stranded molecules are formed (Figure 4)*" (page 27, lines 10 to 12). In the board's judgement, the skilled person thus

reads and construes the disclosure on page 27 of the application in the context of the disclosure relating to Figure 4 of the application.

36. The appellant's argument that pursuant to Rule 43(7) EPC the reference to Figure 4 was not limiting is not found persuasive. Rule 43(7) EPC concerns the form and content of claims and stipulates that where the European patent application contains drawings including reference signs, the technical features specified in the claims should preferably be followed by such reference signs relating to these features, placed in parentheses, if the intelligibility of the claim can thereby be increased. These reference signs are not to be construed as limiting the claim.

37. In contrast, firstly the reference to Figure 4 is contained in the description, and secondly it is not a reference sign either. By referring to the double-stranded molecules of Figure 4, the paragraph on page 27 of the application defines a very specific structure of the double-stranded structure. Moreover, that structure is explicitly explained on page 27 of the application as comprising "*a continuous series of tandem units of the amplified DNA formed by the processive action of strand displacement polymerases (a concatamer). These concatameric DNA products comprise multiple repeats of the amplified template DNA*" (emphasis added, page 27, lines 12 to 16 of the application). Contrary to the appellant's submission, the application therefore does not provide a generic disclosure regarding the structure of the concatamer.

38. In the board's view, the skilled person would understand that the processive action of strand-displacement polymerase on the circular single-stranded

DNA template results in a product in which sense (A) and anti-sense (A') strands alternate while being separated by protelomerase target sequences (PTS). Accordingly, the concatameric DNA product has the following structure:

5' A - PTS - A' - PTS - A - PTS - A' - PTS ... 3'
3' A'- PTS - A - PTS - A'- PTS - A - PTS ... 5'

where A' is the reverse complementary sequence of A.

39. The skilled person would furthermore directly and unambiguously derive from page 27 of the application that the length of the concatamer and the number of units depended on the "*length of the single unit which is to be amplified*" (page 27, line 19 of the application) and that the concatamer did not contain any sequence other than a continuous series of tandem units of the amplified DNA.

40. Since claim 3 is not limited to concatamers having this structure and allows for the presence of further sequences, it presents the skilled person with new technical information not included in the application as filed. For this reason alone, the subject-matter of claim 3 of the main request also extends beyond the disclosure of page 27, lines 5 to 21 of the application. Accordingly, there is no need to assess whether the further features of claim 3 and their combination have a basis in the application on page 27, lines 5 to 21 in combination with page 28, lines 6 to 7.

41. In sum, the board concludes from the above considerations that the subject-matter of claim 3 relates to an unallowable generalisation of the

disclosure of the paragraph bridging pages 3 and 4 and Figures 1 and 4 and the disclosure on page 26 of the application. The subject-matter of claim 3 therefore extends beyond the content of the grandparent application as filed and the claim contravenes Article 76(1) EPC.

42. Since independent claims 1 and 3 add matter, the main request is not allowable. Therefore, the board does not need to give any reasons for holding that dependent claims 2, 4 and 5 also add matter.

*Auxiliary requests I to IV*

43. Auxiliary requests I to IV were newly filed with the statement of grounds of appeal. The respondent requested that these requests not be admitted into the proceedings on the grounds that they contained amendments as per Article 12(4) RPBA which raised complex issues and did not *prima facie* overcome the objections raised in the opposition proceedings.

44. In view of the board's conclusions on allowability under added matter (see below), the question of whether auxiliary requests I to IV should be considered in substance can be left open.

45. Claim 3 of auxiliary requests I to IV is identical to claim 3 of the main request. The observations set out above with respect to claim 3 of the main request equally apply to claim 3 of auxiliary requests I to IV, which therefore also contravene Article 76(1) EPC.

*Conclusion*

46. The main request and auxiliary requests I to IV add matter. Since both independent claims of the main request add matter, the added-matter objection cannot be overcome by deleting one of the independent claims or any of the dependent claims. The board therefore does not need to deal with the appellant's request that it be permitted to delete any of the claims of the main request in order to address the added-matter objection. In the absence of an allowable request, the decision under appeal cannot be set aside and the appeal must be dismissed.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar: The Chairwoman:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated