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**Datasheet for the decision
of 13 May 2016**

Case Number: T 1955/14 - 3.3.08

Application Number: 04015041.9

Publication Number: 1555317

IPC: C12N15/113, A61K48/00,
A01K67/027, C12N5/10

Language of the proceedings: EN

Title of invention:

Synthetic genes and genetic constructs comprising the same

Patent Proprietor:

COMMONWEALTH SCIENTIFIC AND
INDUSTRIAL RESEARCH ORGANISATION

Opponents:

STRAWMAN LIMITED
BASF SE

Headword:

Modulation repression reduction inhibition expression target
gene/CSIRO

Relevant legal provisions:

EPC Art. 76(1), 123(2)
RPBA Art. 13(1)

Keyword:

Decisions cited:

G 0002/10, T 1491/05

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1955/14 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 13 May 2016

Appellant: COMMONWEALTH SCIENTIFIC AND
(Patent Proprietor) INDUSTRIAL RESEARCH ORGANISATION
Limestone Avenue
Campbell, ACT 2612 (AU)

Representative: Almond-Martin, Carol
Ernest Gutmann - Yves Plasseraud S.A.S.
88, Boulevard des Belges
69452 Lyon Cedex 06 (FR)

Respondent: STRAWMAN LIMITED
(Opponent 1) Orchard Lea
Horns Lane
Combe
Witney, Oxfordshire OX29 8NH (GB)

Representative: Potter Clarkson LLP
The Belgrave Centre
Talbot Street
Nottingham NG1 5GG (GB)

Respondent: BASF SE
(Opponent 2) 67056 Ludwigshafen (DE)

Representative: Herzog, Fiesser & Partner Patentanwälte PartG
mbH
Patentanwälte
Dudenstrasse 46
68167 Mannheim (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 11 July 2014
revoking European patent No. 1555317 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman M. Wieser
Members: P. Julià
 D. Rogers

Summary of Facts and Submissions

- I. The appeal lies against the decision of the opposition division to revoke European patent No. 1 555 317, which is based on European patent application No. 04 015 041.9 (hereinafter "*the application as filed*"), a divisional application of the earlier European patent application No. 99 910 039.9 (published as WO 99/49029; hereinafter "*the parent application*"). The opposition division decided that the Main Request and Auxiliary Requests I to III did not fulfil the requirements of Articles 76(1) and 123(2) EPC.
- II. With the statement setting out the Grounds of Appeal, the patentee (appellant) filed a new Main Request and new Auxiliary Requests I to III.
- III. Opponents 01 and 02 (respondents I and II, respectively) replied to appellant's Grounds of Appeal.
- IV. The parties were summoned to oral proceeding. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the parties were informed of the board's preliminary, non-binding opinion on some issues of the case.
- V. Both respondents, without filing substantive arguments, informed the board that they will attend the oral proceedings.
- VI. The appellant filed further submissions and new Auxiliary Request IV.
- VII. Oral proceedings were held on 13 May 2016. At these proceedings, the appellant withdrew the Main Request

and Auxiliary Requests I to III and made its Auxiliary Request IV its new Main Request.

VIII. Claim 1 of the **Main Request** reads as follows:

"1. A synthetic gene which is capable of repressing, delaying or otherwise reducing the expression of a target gene in an animal cell,

wherein said synthetic gene comprises a foreign nucleic acid molecule comprising multiple copies of a nucleotide sequence (a) of greater than 20 nucleotides which is substantially identical to a nucleotide sequence of said target gene,

wherein the multiple copies are presented as an interrupted palindrome sequence,

and the foreign nucleic acid is operably under the control of a single promoter sequence."

IX. The submissions of the appellant, insofar as they are relevant to the present decision, may be summarized as follows:

Admissibility of the Main Request

Claim 1 of the Main Request was identical to claim 1 of the Main Request and Auxiliary Request 1 underlying the decision of the opposition division. The Main Request was a direct and straightforward reply to the board's communication and did not increase the complexity of the case.

Article 100(c) EPC (Articles 76(1) and 123(2) EPC)

The feature "*greater than 20 nucleotides*" in claim 1 had a basis in paragraph [0027] of the application as filed, in particular on page 5, line 3. At the beginning of this paragraph, it was stated that the nucleotide sequence (a) comprised in the foreign nucleic acid molecule didn't need to be full-length relative to the target gene. The full-length of the target gene was disclosed as being the upper-end value of the length of the nucleotide sequence (a) comprised in the foreign nucleic acid molecule. This upper-end value was also present in claim 1 since the nucleotide sequence (a) comprised in the foreign nucleic acid molecule was required to be "*substantially identical*" to the nucleotide sequence of the target gene.

Immediately after the disclosure of this upper-end value, reference was made to several lower-end values. It was directly and unambiguously derivable from this paragraph that all values explicitly disclosed therein were preferred minimum lengths of the nucleotide sequence (a) comprised in the foreign nucleic acid molecule. Thus, the term "*greater than 20-100 nucleotides*" found in this paragraph indicated only a plurality of preferred minimum length values, namely "*greater than 20, greater than 21, greater than 22, ..., greater than 100 nucleotides*". The lowest lower-end value disclosed was "*greater than 20 nucleotides*", i.e. the feature contained in claim 1. According to the established case law, no new subject-matter was created when a disclosed upper-end value (full-length of the target gene) was combined with a disclosed lower-end value (greater than 20 nucleotides). The disclosure on page 8, third paragraph of the parent application was identical to the disclosure in paragraph [0027] of the application as

filed. Thus, the requirements of Articles 76(1) and 123(2) EPC were fulfilled.

If, however, the term "*greater than 20-100 nucleotides*" in paragraph [0027] was considered to be open to interpretation, and was not referring to lower-end length values of the nucleotide sequence (a) comprised in the foreign nucleic acid molecule, but to a particular preferred range ("*greater than 20 nucleotides to 100 nucleotides*"), the length value "20" was also explicitly disclosed as a lower-end length value of this preferred range. Thus, if there was any ambiguity in the disclosure of paragraph [0027], which was denied by the appellant, this ambiguity did not affect the feature "*greater than 20 nucleotides*" because this feature was clearly and unambiguously identified as the lowest lower-end length value in all possible interpretations. The established case law, referred to above, applied also to this "preferred range"-interpretation, so that also from this point of view claim 1 of the Main Request fulfilled the requirements of Articles 76(1) and 123(2) EPC.

In decision T 1491/05 of 24 April 2007, the competent board decided that the feature "*greater than 20 to 100 nucleotides in length*" in claim 1 of the auxiliary request before it contravened Article 84 EPC. However, this decision was not relevant to the present case proceedings because this feature was not present in claim 1 of the Main Request. The requirements, as well as the tests for assessing whether these requirements were met, were different for Articles 76(1) and 123(2) EPC and for Article 84 EPC.

The fact that claim 1 of the application as filed referred to a range ("*about 20-100 nucleotides in*

length") which was different from the values/ranges disclosed in paragraph [0027] ("*greater than 20-100 nucleotides*"), did not change the disclosure given in this paragraph, as it had to be seen as being totally independent.

- X. The submissions of the respondents, insofar as they are relevant to the present decision, may be summarized as follows:

Admissibility of the Main Request

The Main Request was filed only after the communication of the board. It could and should have been filed at an earlier stage of the proceedings because the amendment introduced into this request (deletion of the method-claims) could have been made much earlier. There was no reason to admit it at this late stage of the proceedings, the less so, because the board did not raise any new objections and/or arguments in its communication.

Article 100(c) EPC (Articles 76(1) and 123(2) EPC)

The feature "*greater than 20-100 nucleotides*" in paragraph [0027] of the application as filed was ambiguous and open to multiple interpretations. The values disclosed in this paragraph were not clearly and unambiguously identified as lower-end values of a length range. The ambiguity of this feature became even more outstanding by the length range in claim 1 of the application as filed that was defined in a completely different way ("*about 20-100 nucleotides in length*"). Indeed, the feature "*greater than 20-100 nucleotides*" in paragraph [0027] could also be interpreted as excluding the values "*20-100*" and defining the

preferred sequence of length values as *101, 102, etc.*, by analogy with similar terminology generally used for excluding certain room temperatures ("*greater than 18-26 degrees*"). Moreover, contrary to paragraph [0027] of the application as filed, where the upper-end length value of the nucleotide sequence (a) comprised in the foreign nucleic acid molecule was defined as the length of the target gene, this upper-end value was not present in claim 1 of the Main Request. The feature "*substantially identical to a nucleotide sequence of said target gene*" in claim 1 allowed the nucleotide sequence (a) comprised in the foreign nucleic acid molecule to be longer than the target gene. Therefore, the case law established by the Boards of Appeal concerning the combination of end values of ranges and sub-ranges did not apply to the present situation. The disclosure on page 8, third paragraph of the parent application was identical to the disclosure of paragraph [0027] of the application as filed. Thus, the feature "*greater than 20 nucleotides*" in claim 1 of the Main Request contravened Articles 76(1) and 123(2) EPC.

XI. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the Main Request submitted at the oral proceedings on 13 May 2016.

XII. The respondents requested that the appeal be dismissed.

Reasons for the Decision

Admissibility of the Main Request

1. The new Main Request has been filed in reply to the board's communication pursuant to Article 15(1) RPBA

and thus, after the filing of appellant's statement of Grounds of Appeal and the respondents' reply thereto. The admissibility of the Main Request into the appeal procedure is therefore subject to the board's discretion under Article 13(1) RPBA.

2. The respondent is right when saying that the Main Request could have been filed at an earlier stage of the proceedings, however, it neither increases the complexity of the case nor runs contrary to the need for procedural efficiency. As the appellant has rightly pointed out, claim 1 has been in the appeal proceedings from the beginning and the opposition division has decided on its subject-matter and has given a detailed reasoning why, in its opinion, it did not meet the requirements of Article 100(c) EPC.
3. Therefore, the board, exercising its discretion under Article 13(1) RPBA, decides to admit the Main Request into the appeal proceedings.

Article 100(c) EPC (Articles 76(1) and 123(2) EPC)

4. Claim 1 is directed to a synthetic gene "*capable of repressing, delaying or otherwise reducing the expression of a target gene*", wherein said synthetic gene comprises a foreign nucleic acid molecule comprising multiple copies of a nucleotide sequence (a) characterized in that this sequence (a) is "**greater than 20 nucleotides**" and "*substantially identical to a nucleotide sequence of said target gene*" (cf. point VIII *supra*). The opposition division considered that the first feature did not have a basis in the application as filed or in the parent application and that therefore the requirements of Articles 76(1) and

123(2) EPC were not met (cf. pages 6-7, point 13.3 of the decision under appeal).

5. According to decision G 2/10 (OJ EPO 2012, page 376) which makes reference to other decisions of the Enlarged Board of Appeal concerned with Article 123(2) EPC, the "gold" standard for assessing compliance with Article 123(2) EPC is to establish whether the skilled person is presented with technical information which is derived **directly and unambiguously**, using common general knowledge, from the application as filed. In the present case, it is not disputed that paragraph [0027] of the application as filed is the sole possible basis for the feature "*greater than 20 nucleotides*". This paragraph is identical word-for-word with the disclosure present on page 8, third paragraph of the parent application.

6. Several properties of the nucleotide sequence (a) comprised in the foreign nucleic acid molecule are defined in paragraph [0027] of the application as filed. In particular, it is stated that the length of the sequence (a) "*need not be full length, relative to ... the target gene. A higher homology in a shorter than full length sequence compensates for a longer less homologous sequence*". Immediately thereafter, it is said that "*a sequence of **greater than 20-100 nucleotides** should be used, though a sequence of greater than about 200-300 nucleotides would be preferred, and a sequence of greater than 500-1000 nucleotides would be especially preferred depending on the size of the target gene*" (emphasis added by the board). Thus, there is no literal basis for the feature "*greater than 20 nucleotides*" in paragraph [0027] of the application as filed.

7. From the arguments put forward by the parties and the discussion concerning the disclosure in paragraph [0027] of the application as filed, the board concludes that the feature "*greater than 20-100 nucleotides*" is open to at least two interpretations, wherein each of these interpretations is open to different possible readings.

7.1 According to a first interpretation, paragraph [0027] starts by defining the upper-end length value (maximum length) of the nucleotide sequence (a) to be the full-length of the target sequence and then defines various preferred lower-end length values (**minimum length**) of said sequence. The selection of a specific minimum length may then be made "*depending on the size of the target gene*".

7.1.1 The appellant argued that, following this interpretation, the feature "*greater than 20-100 nucleotides*" had to be understood as defining a plurality of ranges with specific minimum values, such as "*greater than 20, greater than 21, ... greater than 100*", up to the maximum length. The term "*greater than*" would not only qualify the two-end values ("*greater than 20 nucleotides*" and "*greater than 100 nucleotides*") but also all intermediate values. In this case, the feature "*greater than 20 nucleotides*" in claim 1 would define a range from 21 nucleotides to the full-length of the target sequence.

However, the board is not convinced that this is the correct (let alone the only) way of reading the crucial disclosure in paragraph [0027]. When drafting a patent application, the disclosure of a preference among several values is usually defined in a hierarchical manner ("*greater than 20 nucleotides, more preferred*

greater than 50 nucleotides, especially preferred greater than 100 nucleotides"). The indication of the lower-end value as a range ("20-100") cannot be reasonably interpreted as meaning "*greater than 20, more preferably greater than 100*".

- 7.1.2 The respondents have argued that, in an analogy with an often used way to exclude specific room temperatures ("*greater than 18-26 degrees*"), the term "*greater than*" in connection with a range, does not qualify the explicit end values of the range but the particular (sub)range disclosed. Thus, the term "*greater than 20-100 nucleotides*" was understood to mean that the preferred values for the minimum length of the nucleotide sequence (a) comprised in the foreign nucleic acid molecule were "*greater than (20-100) nucleotides*", thus "*101, 102, ... nucleotides*" (cf. point X *supra*).

This was strongly contested by the appellant, who argued that such construction was not normally used in the drafting of patent applications and was not derivable in any way from the application as filed or the parent application.

- 7.1.3 Thus, although the board is not convinced that any of these two ways of reading suggested by the parties is the correct one, notes that only one of them (i.e. the appellant's one) would provide a basis for the disclosure of the feature "*greater than 20 nucleotides*" as a minimum length of the nucleotide sequence (a).

- 7.2 According to a second interpretation, the disclosure in paragraph [0027] of the application as filed defines, first, the upper-end length value (maximum length) of the nucleotide sequence (a) to be the full-length of

the target sequence and, then, the preferred **length ranges** of said nucleotide sequence (a). The selection of a preferred range may be then made "*depending on the size of the target gene*".

7.2.1 In that case, the term "*greater than 20-100 nucleotides*" is understood as "*greater than 20 **to** 100 nucleotides*", wherein the term "*greater than*" qualifies only the lower-end value (i.e. "20"). Thus, the disclosure in paragraph [0027] would define several preferred sub-ranges, which are considerably smaller than the largest possible length of the nucleotide sequence (a), i.e. the full-length of the target sequence (1385 bp in length; Example 1 of the application as filed). Other length values, smaller than this largest value but not within the indicated sub-range, although not preferred, would not be excluded. The board notes, that this interpretation has been adopted by the competent board in decision T 1491/05 (*supra*) when examining clarity of the auxiliary request before it (cf. *supra*, point 10 of the Reasons).

7.2.2 Moreover, it cannot be excluded that the disclosure in paragraph [0027] of the application as filed is understood as defining several preferred length ranges *per se*, which are not sub-ranges within the full-length of the target sequence. In that case, these length ranges are actual alternatives to the full-length of the target sequence and thereby, all other (intermediate) values or length ranges within the largest length are - for whatsoever reason - excluded. These would indeed be the case for length values falling within the ranges 101-200, 301-500, etc. (cf. page 8, last paragraph of respondent II's reply to appellant's Grounds of Appeal). This reading is, as

argued by the respondents, in line with the wording of claim 1 of the application as filed, where a nucleotide sequence is defined as of "*about 20-100 nucleotides in length*", a length range that excludes all other values (see page 7, two last sentences, first paragraph of the decision under appeal).

7.2.3 For both ways of reading the disclosure in paragraph [0027] according to the second interpretation, it is an important fact that a particular upper-end length value is present for all sub-ranges/ranges disclosed. For the preferred sub-range/range of "*greater than 20-100 nucleotides*", the upper-end value is "*100 nucleotides*". The deletion of this particular upper-end length value creates a completely new, open-ended range for which no support can be found in paragraph [0027] when understood as defining length-ranges (cf. point 7.2.2 *supra*).

7.2.4 Moreover, when understanding paragraph [0027] as defining length sub-ranges (cf. point 7.2.1 *supra*), the full-length of the target sequence is disclosed in this paragraph as the upper-end value limiting the length of all sub-ranges. However, the feature "*substantially identical to a nucleotide sequence of said target gene*" in claim 1 of the Main Request does not exclude sequences which are longer than said target sequence (cf. paragraphs [0062]-[0063] of the application as filed).

8. As a consequence of these different interpretations of the crucial feature of claim 1 and the various possible readings thereof, the decisions of the Boards of Appeal, referred to by the appellant to support its line of arguments, do not apply to the present appeal case. On the one hand, the feature "*greater than 20*

nucleotides" is not clearly and unambiguously identified as a lower-end length value in the application as filed (cf. point 7.1 *supra*) and, on the other hand, the upper-end length value disclosed in paragraph [0027] of the application as filed is not clearly defined in claim 1 of the Main Request (cf. point 7.2 *supra*).

9. Thus the feature "*greater than 20 nucleotides*" in claim 1 of the Main Request cannot be derived by the skilled person directly and unambiguously, using common general knowledge, from the application as filed. Hence, the requirements of Article 123(2) EPC are not complied with (cf. point 5 *supra*). Since the relevant parts of the description of the parent application are word-for-word identical with the respective parts of the application as filed (cf. page 8, third paragraph of the parent application and paragraph [0027] of the application as filed), also the requirements of Article 76(1) EPC are not met.
10. The Main Request does not fulfil the requirements of Articles 76(1) and 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated