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Datasheet for the decision of 25 March 2024

Case Number: T 1619/22 - 3.4.02

Application Number: 15834247.7

Publication Number: 3185004

IPC: G01N23/201, C07K16/00, G01N11/00, C07K16/18

Language of the proceedings: EN

Title of invention:
METHOD FOR MEASURING VISCOSITY OF PROTEIN SOLUTION

Applicant:
Chugai Seiyaku Kabushiki Kaisha

Headword:

Relevant legal provisions:
EPC Art. 111(1), 123(2)
RPBA 2020 Art. 11

Keyword:
Amendments - added subject-matter (no)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

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Office européen des brevets

Beschwerdekammern

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Case Number: T 1619/22 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 25 March 2024

Appellant: (Applicant)	Chugai Seiyaku Kabushiki Kaisha 5-1, Ukima 5-chome Kita-ku Tokyo 115-8543 (JP)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 February 2022 refusing European patent application No. 15834247.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	R. Bekkering
Members:	A. Hornung
	C. Almberg

Summary of Facts and Submissions

I. The applicant (appellant) appealed against the decision of the examining division refusing European patent application No. 15834247.7 on the basis of Article 97(2) EPC because none of the requests then on file was compliant with the requirement of Article 123(2) EPC.

II. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the claims in accordance with the main request or one of the first to third auxiliary requests, all requests underlying the appealed decision and re-filed together with the statement setting out the grounds of appeal.

III. Claim 1 of the main request reads as follows:

"A method for estimating viscosity of a protein solution, which comprises the steps of:
1) irradiating a sample of the protein solution with an X-ray, wherein the protein concentration in the sample is 10 mg/mL to 100 mg/mL to determine apparent maximum particle diameter (D_{max}^{app}), apparent particle radius of gyration (R_g^{app}), or apparent molecular weight by a small angle X-ray scattering (SAXS) method or X-ray solution scattering method; and
2) calculating viscosity of the protein solution from the above-determined value based on a calibration curve obtained in advance, wherein the protein solution has a protein concentration higher than the concentration of the sample in step 1)".

Claim 6 of the main request reads as follows:

"A method for producing a modified protein with decreased viscosity in solution, which comprises the steps of:
1) obtaining modified proteins by modifying portions of the amino acids of an original protein;
2) estimating viscosity of the modified protein solutions by using a method according to claim 1; and
3) selecting from the modified proteins, a modified protein with viscosity in solution lower than that of the original protein".

Reasons for the Decision

1. Main request - Article 123(2) - claim 1

Claim 1 is not amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).

1.1 Objection raised by the examining division

According to the appealed decision, claim 1 contravenes the requirement of Article 123(2) for the sole reason that there is no basis in the patent application as originally filed for the amended feature "wherein the protein solution has a protein concentration higher than the concentration of the sample in step 1)".

The examining division is of the opinion that the disclosure on page 6, lines 12 to 14, of the patent application as originally filed "has to be seen in a broader context, namely that the concentration is relatively low compared to any other reference. The passage does not specify that the sample has a lower concentration than the protein solution. Narrowing down the disclosure to the specific interpretation is not

considered appropriate in view of the disclosure as a whole. Moreover, the passage does not provide any concentration that is lower than the concentration of the sample in the range of 10 mg/mL to 100 mg/mL.

Thus this passages *[sic]* does not provide a basis for the amendment of claim 1. This lack of original disclosure cannot be overcome by taking the passage on p.6, II. 15-21 into account, as this passage is silent with respect to providing a relation in the sense of any lower concentration of the sample compared to the concentration of the protein solution" (decision, reasons 21).

1.2 The board is not convinced by the examining division's arguments.

1.2.1 The passage on page 6, lines 12 to 14, of the patent application as originally filed reads:

> "In the method of the present invention, even a small amount of a protein solution at a relatively low concentration can be used to accurately estimate its viscosity at a high concentration".

From this passage, the skilled person is taught that one of the objectives of the invention is to estimate the viscosity of a protein solution at a high concentration. Moreover, the skilled person is taught that this viscosity of the protein solution at a high concentration is not directly measured by using this protein solution at the high concentration, but by using a small amount (i.e. a sample) of the protein solution at a relatively low concentration.

Therefore, while the terms "high" and "low" as such are relative terms without a precise meaning on their own, in

the present situation where both terms characterise the same parameter of protein concentration, the meaning of the terms "high" and "low" has a precise meaning in the sense that the estimation of the viscosity is carried out by using a protein solution with a lower protein concentration than the protein solution whose viscosity is actually to be measured. In other words, the protein solution whose viscosity is to be estimated has a higher protein concentration than the protein concentration of the sample used for the estimation. This teaching derived from page 6, lines 12 to 14, of the patent application as originally filed, corresponds to the amended feature of claim 1.

Since the amended feature of claim 1, objected by the examining division, is directly and unambiguously derivable from the passage on page 6, lines 12 to 14, of the patent application as originally filed, claim 1 has not been amended in such a way that it contains subject-matter which extends beyond the application as originally filed.

1.2.2 The passage on page 6, lines 15 to 21, of the patent application as originally filed reads:

> "Specifically, by (1) irradiating a sample with 1 mg/mL to 100 mg/mL protein concentration with an X-ray, and using the small angle X-ray scattering (SAXS) method or the X-ray solution scattering method to determine apparent particle size (apparent maximum particle diameter (D_{max}^{app}) or apparent particle radius of gyration (R_g^{app})) *[sic]* or apparent molecular weight; and (2) calculating the viscosity of the protein from the above-determined value based on a calibration curve obtained in advance, one can

estimate the viscosity of the protein-containing solution at a high concentration".

This passage is explicitly linked to the preceding passage on page 6, lines 12 to 14, of the patent application as originally filed by the term "specifically". From this passage on page 6, lines 15 to 21, of the patent application as originally filed, the skilled person learns how the sample of protein solution with a relatively low concentration, referred to in the preceding paragraph on page 6, lines 12 to 14, of the original patent application is effectively used to estimate the viscosity of the protein solution with a high concentration (X-ray scattering methods; calibration curve). Indeed, this passage on page 6, lines 15 to 21, of the patent application as originally filed concludes with the statement "one can estimate the viscosity of the protein-containing solution at a high concentration", so that it is clear to the skilled person that the term "high" is to be understood as meaning "higher than the concentration of the protein solution used in the X-ray scattering methods".

This passage further teaches the skilled person that the relatively low concentration of the sample irradiated by the X-ray means a concentration between 1 mg/mL to 100 mg/mL. The fact that the concentration range defined in present claim 1 is more limited, i.e. 10 mg/mL to 100 mg/mL, has a clear basis in claim 2 as originally filed.

Therefore, the passage on page 6, lines 15 to 21, of the patent application as originally filed corroborates the finding that the amended feature of claim 1 is directly and unambiguously derivable from the patent application as originally filed.

2. Main request - Article 123(2) - claim 6

Claim 6 is not amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC.

2.1 Objection raised by the examining division

2.1.1 According to the appealed decision, the requirements of Article 123(2) EPC are not met for claim 6 for the following reasons:

"The following basis in the original application was indicated for claim 6 of the MR: orignal claims *[sic]* 16 with its back reference to original 12 *[sic]*, p.6, ll. 22-23 and p.7, l.32-36 ("selecting"), p.6, l.6 ("estimate"). Example 5 was provided as an exemplification of the method.

The method of original claim 12 corresponds to step 1) of original claim 1, However *[sic]*, the preamble of claim 12 reads 'A method for selecting a viscosity-regulated protein', the preamble of claim 16 reads 'A method for producing a modified protein with decreased viscosity', the preamble of original claim 1 reads 'A method for measuring viscosity of a protein solution' and the preamble of actual claim 1 reads 'A method for estimating viscosity of a protein solution'.

This analysis shows that the purpose of the methods of original claims 12 and 1 differed from each other. It is not obvious from the original disclosure that a combination of the methods of original claims 16 and 1 was intended, as original claim 16 explicitly referred back to claim 12, which refers to a method that has a purpose that is different from the purpose of the method of claim 1.

The passage on p.7, ll. 32-26 discloses that the method of the invention can be used to select (screen) proteins with reduced viscosity and to produce such proteins, however this passage does not point the skilled person to combine methods that have different purposes to arrive at the exact combination of features of actual claim 6".

2.1.2 In other words, the examining division is of the opinion that since original claim 16, on which present claim 6 is at least partly based, refers only to original claim 12, i.e. to a method for *selecting* a protein, there was no basis for present claim 16 to refer to another method, such as a method for *estimating* viscosity as defined in present claim 1.

2.2 The board does not agree with the examining division's view.

2.2.1 Original claim 16, in order to select a modified protein with viscosity lower than that of the original protein, refers explicitly to original claim 12 defining a method for selecting a viscosity-regulated protein. However, the method of original claim 12 for selecting a viscosity-regulated protein does not comprise such a concrete selecting step. Therefore, it is clear to the skilled person that a concrete and more precise selecting step has to be added to the method of original claims 16 and 12.

2.2.2 As explicitly defined in original claim 16, this missing selecting step must enable the skilled person to select a protein with viscosity lower than that of the original protein. As taught in the patent application as originally filed, page 6, lines 22 and 23, and page 7, lines 32 to 36, methods for predicting or estimating protein viscosity "can be used to efficiently select (screen) viscosity-

regulated proteins, proteins with reduced viscosity, or modified low-viscosity proteins, and to efficiently produce such modified proteins" (page 7, lines 32 to 36). This means that the patent application as originally filed teaches that selecting a modified protein with viscosity lower than that of the original protein requires estimating the viscosity of the modified protein. Since present claim 1 defines such a method for estimating viscosity of a protein solution, the referral in present claim 6 to present claim 1 does not add any new information to the original disclosure of the patent application.

2.2.3 In conclusion, as essentially submitted by the appellant in its statement of grounds of appeal, point 3.1, present claim 6 is directly and unambiguously derivable from original claims 16 and 12, in combination with the passages of the patent application as originally filed on page 6, lines 22 and 23, and on page 7, lines 32 and 26.

3. Remittal; decision in written procedure

3.1 Since the board is not convinced by the argumentation of added subject-matter as provided by the examining division, the appealed decision must be set aside.

3.2 The decision under appeal dealt only with the issue of added subject-matter without considering any of the other requirements of the EPC, especially clarity, novelty and inventive step. The significant scope of the pending examination would require the board to go far beyond the primary object of the appeal proceedings to review the appealed decision in a judicial manner (Article 12(2) RPBA). This constitutes a "special reason" within the meaning of Article 11 RPBA. Therefore, the board considers it appropriate to remit the case to the examining division

for further prosecution under Article 111(1), second sentence, EPC.

3.3 With this outcome, there is no request for, and also no expedience to gain in holding any oral proceedings. As the appellant's comments in the statement of grounds pertain to the grounds of this decision all conditions are met for handing it down in written procedure (Article 12(8) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

L. Gabor R. Bekkering

Decision electronically authenticated