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Datasheet for the decision of 24 April 2019

Case Number: T 0721/16 - 3.3.03

Application Number: 08001338.6

Publication Number: 1950230

IPC: C08F126/10

Language of the proceedings: EN

Title of invention:
Polyvinylpyrrolidone powder compositions

Patent Proprietor:
NIPPON SHOKUBAI CO., LTD.

Opponent:
BASF SE

Relevant legal provisions:
EPC Art. 123(2), 83, 111(1)

Keyword:
Amendments - Main request - allowable (no) - First auxiliary request - allowable (yes)
Sufficiency of disclosure - First auxiliary request - (yes)
Appeal decision - remittal to the department of first instance (yes)

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Case Number: T 0721/16 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 24 April 2019

Appellant: (Patent Proprietor)	NIPPON SHOKUBAI CO., LTD. 1-1, Koraibashi 4-chome Chuo-ku Osaka-shi, Osaka (JP)
Representative:	Müller-Boré & Partner Patentanwälte PartG mbB Friedenheimer Brücke 21 80639 München (DE)
Respondent: (Opponent)	BASF SE 67056 Ludwigshafen (DE)
Representative:	BASF SE Global Intellectual Property GVX/D - C6 67056 Ludwigshafen (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 January 2016 revoking European patent No. 1950230 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	F. Rousseau
Members:	D. Marquis
	R. Cramer

Summary of Facts and Submissions

I. The appeal lies against the decision by the opposition division, posted on 27 January 2016, revoking the European patent No. 1 950 230.

II. The application as filed contained five claims among which claims 1-3 were independent claims reading:

"1. A polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 50 and not higher than 120, wherein a content of insoluble substances remaining on a membrane filter having a pore size of 1.2 μm when a 2 wt% aqueous solution of the composition is filtered with the filter is not higher than 70 ppm."

"2. A polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 50 and not higher than 120, wherein a K value lowering ratio to be observed when the composition is heated at 80°C in air for 14 days is not higher than 12%."

"3. A polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 50 and not higher than 120, wherein a content of insoluble substances remaining on a membrane filter having a pore size of 1.2 μm when a 2 wt% aqueous solution of the composition is filtered with the filter is not higher than 70 ppm, and a K value lowering ratio to be observed when the composition is heated at 80°C in air for 14 days is not higher than 12%".

III. A notice of opposition against the patent was filed, requesting the revocation of the patent on the grounds that the subject matter of the patent lacked novelty and inventive step (Article 100(a) EPC) and was not sufficiently disclosed (Article 100(b) EPC).

IV. The decision of the opposition division was announced at the oral proceedings on 20 November 2015. The decision was based on a main request filed with letter of 17 September 2015 and on the first to third auxiliary requests filed at the oral proceedings before the opposition division.

The main request contained three independent claims reading:

"1. A polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 55 and not higher than 120, wherein a content of insoluble substances remaining on a membrane filter having a pore size of 1,2 µm when a 2 wt% aqueous solution of the composition is filtered with the filter is not higher than 70 ppm and wherein the powder composition is produced by at least one method selected from the group consisting of (1) adjusting the pH of a polymerization solution using a secondary amine before, during, and/or after the polymerization, (2) carrying out a filtration operation after completion of the polymerization and drying by means of a heating surface adhesive-type drying method, a freeze drying method, or a vacuum drying method, and (3) drying by means of a freeze drying method or a vaccum drying method after completion of the polymerization while maintaining the internal temperature at 50°C or lower by dropping polymerization using a polymerization

initiator usable at low temperatures."

"2. A polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 55 and not higher than 120, wherein a K value lowering ratio to be observed when the composition is heated at 80°C in air for 14 days is not higher than 12% and wherein the powder composition is produced by at least one method selected from the group consisting of (1) adjusting the pH of a polymerization solution using a secondary amine before, during, and/or after the polymerization, and (4) adding an organic acid or an aqueous solution thereof to a polymerization solution, adjusting the pH of the polymerization solution using a base, other than secondary amines, or an aqueous solution thereof, and then adding an antioxidant to the polymerization solution before, during, and/or after the polymerization."

"3. A polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 55 and not higher than 120, wherein a content of insoluble substances remaining on a membrane filter having a pore size of 1.2 μm when a 2 wt% aqueous solution of the composition is filtered with the filter is not higher than 70 ppm, and a K value lowering ratio to be observed when the composition is heated at 80°C in air for 14 days is not higher than 12% and wherein the powder composition is produced by (1) adjusting the pH of a polymerization solution using a secondary amine before, during, and/or after the polymerization, or a combination of (1) adjusting the pH of a polymerization solution using a secondary amine before, during, and/or after the polymerization, (2) carrying out a filtration operation after completion of the polymerization and drying by means of a heating

surface adhesion-type drying method, a freeze drying method, or a vacuum drying method, and/or (3) drying by means of a freeze drying method or a vacuum drying method after completion of the polymerization while maintaining the internal temperature at 50°C or lower by dropping polymerization using a polymerization initiator usable at low temperatures, with (4) adding an antioxidant to the polymerization solution before, during, and/or after the polymerization, and when method (1) is not employed, adding an organic acid or an aqueous solution thereof to a polymerization solution, and adjusting the pH of the polymerization solution using a base, other than secondary amines, or an aqueous solution thereof."

The first auxiliary request contained three independent claims. Claim 1 of that request corresponded to claim 1 of the main request with the exception of "1.2 µm" instead of "1,2 µm" and "polymerization (2)" instead of "polymerization, (2)".

Claim 2 of that request corresponded to claim 2 of the main request in which step (4) was amended as follows (addition in bold, deletions in strikethrough by comparison with the main request):

"~~,~~ and (4) adding an organic acid or an aqueous solution thereof to a polymerization solution **after polymerization**, adjusting the pH of the polymerization solution using a base, other than secondary amines, or an aqueous solution thereof, and ~~then~~ adding an antioxidant to the polymerization solution ~~before, during, and/or~~ after the polymerization."

Claim 3 of that request corresponded to claim 3 of the main request with the following addition to the proviso

at the end of the claim (addition in bold by comparison with the main request):

"and when method (1) is not employed, adding an organic acid or an aqueous solution thereof to the polymerization solution **after polymerization**, and adjusting the pH of the polymerization solution using a base other than secondary amines, or an aqueous solution thereof".

Auxiliary request 2 was based on claim 3 of the main request as sole claim in which the claimed composition was produced by the first production process.

Auxiliary request 3 was based on a single method claim reading:

"1. A method for producing a polyvinylpyrrolidone powder composition comprising polyvinylpyrrolidone with a K value of not lower than 55 and not higher than 120, wherein a content of insoluble substances remaining on a membrane filter having a pore size of 1.2 µm when a 2 wt% aqueous solution of the composition is filtered with the filter is not higher than 70 ppm, and a K value lowering ratio to be observed when the composition is heated at 80°C in air for 14 days is not higher than 12%, wherein the method comprises adjusting the pH of a polymerization solution using a secondary amine before, during, and/or after the polymerization".

V. The decision of the opposition division was taken having regard to experimental data filed by the opponent with letter of 26 August 2015. As far as it is relevant to the present case, the decision can be summarized as follows:

(a) The definition of step (4) in claim 2 of the main request found no basis in the application as filed. In particular, the wording of claim 2 implied that the organic acid could also be added before polymerization. However, the description as filed disclosed that organic acid was added to the reaction solution, which corresponded to the solution during and/or after the polymerization. Nowhere in the original disclosure was it disclosed that organic acid could be added before the polymerization. That objection against claim 2 also applied to claim 3 as it contained the same wording. Neither claim 2 nor claim 3 fulfilled the requirements of Article 123(2) EPC.

(b) The objection of lack of sufficiency of disclosure related to two parameters, the content of insolubles and the K value lowering ratio of the polyvinylpyrrolidone powder composition. In that respect, the experimental report provided by the opponent on 26 August 2015 contained a repetition of examples 1, 2, 4, 5 and comparative examples 1 and 2 of the patent in suit. It showed that measured values of the content of insolubles and the K value lowering ratio differed depending on whether they were taken from the patent in suit or from the rework presented in Tables 1 and 3 of the report, the data contradicting the data shown in Table 1 of the patent. However, since the data were comparable, the benefit of the doubt was given to the proprietor.

(c) With regard to the reproducibility of the measurements however, the data contained in Table 2 of the same report showed that the measurement of the content of insoluble substances for a polymer

obtained according to example 1 of the patent in suit was subject to large variations when it was measured by different technicians. A skilled person following the measurement method disclosed in the patent in suit was thus not in a position to arrive at the claimed polyvinylpyrrolidone powder compositions in a reproducible manner. Consequently, the first auxiliary request did not meet the requirements of Article 83 EPC.

(d) The second and third auxiliary requests also related to method (1) which was used to prepare the composition of example 1 of the patent in suit. The conclusion reached for the first auxiliary request thus also applied to the second and third auxiliary requests.

VI. The patent proprietor (appellant) lodged an appeal against the above decision. With the statement setting out the grounds of appeal the appellant filed a main request and four auxiliary requests.

VII. The respondent filed their rejoinder to the statement setting out the grounds of appeal on 21 October 2016.

VIII. In addition to the experimental report of the opponent filed on 26 August 2015, the following experimental reports were filed in appeal proceedings:

- Annex A, rework of examples 1, 2, 4, 5 and comparative examples 1 and 2 of the patent in suit, dated 31 May 2016 and filed with the statement setting out the grounds of appeal

- Annex I, rework of examples 1, 2 and comparative example 1, and Annex II, reproducibility of the

filtration step with a product according to example 1 of the patent in suit, both annexes filed with the rejoinder to the statement setting out the grounds of appeal

- Report PR 00311/1, Determination of the K-value of Polyvinylpyrrolidone, dated 6 October 2016 and report from Dr. Weyandt, SGS Institut Fresenius GmbH, "Quantification of insoluble PVP according to method described in EP 1 950 230", dated 30 September 2016, both filed by the respondent with letter of 23 May 2017

- Annex B, Certificate of experimentation results, on example 1 of the patent in suit, dated 6 September 2017 and Annex C, certificate of analysis, Polyvinylpyrrolidone example 1, dated 18 August 2017, both filed by the appellant with letter of 26 September 2017

- Laboratory journals showing the protocols followed for the rework of examples 1 and 2 and comparative example 1 of the patent in suit filed by the respondent with letter of 28 February 2019.

IX. The appellant filed with letter of 22 March 2019 a new main request and auxiliary requests 1 to 9.

The main request was identical to the main request filed on 17 September 2015 and decided upon by the opposition division with the exception of the clerical modification of "1,2 µm" in "1.2 µm" in claim 1.

The first auxiliary request contained three independent claims. Claim 1 of that request corresponded to claim 1 of the main request.

Claim 2 of that request corresponded to claim 2 of the main request in which step (4) was amended as follows (addition in bold, deletions in strikethrough by comparison with the main request):

"(4) adding an organic acid or an aqueous solution thereof to ~~a~~ **the** polymerization solution **after polymerization**, adjusting the pH of the polymerization solution using a base, other than secondary amines, or an aqueous solution thereof, and ~~then~~ adding an antioxidant to the polymerization solution ~~before, during, and/or~~ after the polymerization."

Claim 3 of that request corresponded to claim 3 of the main request in which step (4) was amended as follows (addition in bold, deletions in strikethrough by comparison with the main request):

"(4) adding an antioxidant to the polymerization solution before, during, and/or after the polymerization, and when method (1) is not employed, adding an organic acid or an aqueous solution thereof to ~~a~~ **the** polymerization solution **after polymerization**, and adjusting the pH of the polymerization solution using a base, other than secondary amines, or an aqueous solution thereof."

X. Oral proceedings were held on 24 April 2019.

XI. The appellant's arguments, insofar as relevant to the present decision, may be summarised as follows:

Main request

Amendments

(a) The amendments in claims 2 and 3 of the main request found a basis in paragraphs 62, 74, 80 and 82 of the description of the A1-publication of the application. The requirements of Article 123(2) EPC were thus met.

First auxiliary request

Amendments

(b) The modifications in claims 2 and 3 of the first auxiliary request also found a basis in paragraphs 62, 74, 80 and 82 of the A1-publication of the application. The requirements of Article 123(2) EPC were thus met.

Sufficiency of disclosure

(c) The patent in suit provided a detailed description of four methods that could be used to prepare the claimed compositions and contained very detailed examples in which the necessary guidance to obtain the claimed compositions could be found. The experimental data provided in appeal (Annexes A, B and C) further showed that the compositions described in the examples of the patent in suit could be prepared with the guidance provided and that these compositions were according to the claims of the first auxiliary request.

(d) Furthermore, the description of the rework of the examples of the patent in suit in the experimental evidence provided by the respondent in appeal was so incomplete that it did not allow the appellant

to assess why the measurements performed showed such a large variation.

(e) Also, the objection of the respondent solely concerned the accuracy of the methods of measurement of the K value and the content of insoluble substances of the compositions. That objection did not pertain to the sufficiency of disclosure of the claimed compositions.

XII. The respondent's arguments, insofar as relevant to the present decision, may be summarised as follows:

Main request

Amendments

(a) The modification of the wording of step (4) in claim 2 of the main request did not fulfil the requirements of Article 123(2) EPC as it allowed the addition of organic acid before the polymerization reaction, which did not have a basis in the application as filed. The same applied to claim 3.

First auxiliary request

Amendments

(b) There was no objection against the modifications made to the claims of the first auxiliary request.

Sufficiency of disclosure

(c) As acknowledged in the decision under appeal, the experimental report dated 26 August 2015 showed, in

particular with regard to the content of insoluble substances (Table 2), that the patent in suit did not sufficiently disclose the filtration applied during the measurement of that property. The lack of guidance in the patent in suit did not allow the person skilled in the art to ensure whether a polyvinylpyrrolidone powder composition prepared according to the method disclosed in the examples of the patent in suit was within the ambit of the claims or not.

(d) The further experimental evidence submitted in appeal (Annex I) confirmed that the content of insoluble substances measured according to the patent in suit showed an unreasonably large standard deviation.

(e) Annex II submitted with the rejoinder to the statement setting out the grounds of appeal showed that the filtration system, the frit, the pressure applied during the filtration and the volume of the solution filtered were parameters that had a significant influence on the value of the content of insoluble substances obtained. None of these parameters necessary to obtain a reliable value of the content of insoluble substances were described in the patent in suit. In that respect too, the patent in suit lacked sufficiency of disclosure.

(f) The report "PR 00311/1" from Dr. Weyandt and the laboratory journals containing the protocols followed for the rework of examples 1 and 2 and comparative example 1 of the patent in suit showed that the compositions tested in Annexes I and II had been obtained according to the methods disclosed in the patent in suit. The report further

established that the discrepancies between the measurements of the K value, K value lowering ratio and content of insoluble reported in Annexes I and II and in the patent in suit were due to the insufficient disclosure of the methods of measurements of these parameters in the patent in suit.

XIII. The appellant requested that the decision under appeal be set aside and the case be remitted to the department of first instance for further prosecution on the basis of the claims of the main request, or on the basis of the claims of one of auxiliary requests 1 to 9, all filed with the letter of 22 March 2019.

XIV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. Amendments

1.1 The objection of the respondent with regard to Article 123(2) EPC against the main request concerned the formulation of the method of production (4) of the claimed polyvinylpyrrolidone powder compositions of claims 2 and 3. By comparison with claim 2 of the application as filed, claim 2 of the main request additionally defines four methods for the production of the claimed polyvinylpyrrolidone powder compositions, among which, the fourth method which consists in "(4) adding an organic acid or an aqueous solution thereof to a polymerization solution, adjusting the pH of the polymerization solution using a base, other than

secondary amines, or an aqueous solution thereof, and then adding an antioxidant to the polymerization solution before, during, and/or after the polymerization". The question that had to be answered was whether the addition of an organic acid or an aqueous solution thereof to the polymerization solution referred in claim 2 had a basis in the application as filed.

1.2 Among paragraphs 62, 74, 80, 82 of the A1 publication, which were cited by the appellant as a basis for claim 2 of the main request, only paragraphs 80 and 82 concern method (4) and only paragraph 82 actually describes the addition of organic acid or an aqueous solution thereof which is directly relevant to the question posed under Article 123(2) EPC. With regard to the addition of organic acid, paragraph 82 discloses that it is added to a reaction solution, a wording that is different from that used in claim 2 of the main request since in claim 2, the organic acid is said to be added to a polymerization solution.

1.3 The term "reaction solution" is not defined in paragraph 82 but its meaning is implicit from the preceding paragraph 81 which belongs to the description of method (4) and which discloses that organic acid is actually added to the reaction solution after the polymerization reaction, in order to reduce the amount of residual monomer, i.e. the amount of monomer remaining in the reaction solution.

1.4 Thus, the passages cited by the appellant in the A1 publication concerning method (4) defining claim 2 of the main request only provide a basis for the addition of organic acid to the reaction solution after polymerization, which however is not explicit from the

wording of operative claim 2.

1.5 Nevertheless, the question arises whether the term "polymerization solution" of claim 2 of the main request, in the context of that claim, could be seen as being the same thing as the reaction solution after the polymerization reaction disclosed in paragraphs 81-82 of the A1 publication of the application.

1.6 That question can be answered in the negative. The definition of method (4) in claim 2, besides the addition of organic acid, also contains the step of "adding an antioxidant to the polymerization solution before, during, and/or after the polymerization". That wording makes it clear that the term "polymerization solution" does not necessarily refer to the solution after polymerization since it also indicates that an antioxidant can be added to the polymerization solution before or during that polymerization. The description of the addition of antioxidant in method (4) also unambiguously refers to "the polymerization solution" which means that the polymerization solution to which the antioxidant is added is the same as that to which organic acid is added. Not least for reasons of consistency, there is no reason within claim 2 to give to the term "polymerization solution" a different meaning when it is used in the context of the addition of an antioxidant or an organic acid. It is concluded that the term "polymerization solution" in claim 2 of the main request has in fact a broader meaning than the reaction solution after polymerization disclosed in the passage concerning method (4) in the application as filed since it also encompasses the addition of organic acid before or during polymerization.

1.7 No further passage of the application as filed was cited in support of the argument that the subject matter of claim 2 of the main request does not extend beyond the content of the application as filed.

1.8 Claim 2 of the main request does therefore not fulfil the requirements of Article 123(2) EPC.

First auxiliary request

2. Amendments

2.1 Claim 2 of the first auxiliary request was amended in that the definition of method (4), and in particular the addition of the organic acid or aqueous solution thereof is limited to the "polymerization solution after polymerization". Claim 3 of the first auxiliary request, which contains a method corresponding to method (4) in claim 2, has also been amended accordingly. The amendments performed in claims 2 and 3 are supported by the passage defining the fourth preparation of the polyvinylpyrrolidone powder compositions on page 39 of the application as filed.

2.2 The respondent did not object to the first auxiliary request in view of Article 123(2) EPC.

2.3 In view of the above, the Board concludes that the first auxiliary request satisfies the requirements set out in Article 123(2) EPC.

3. Sufficiency of disclosure

3.1 In accordance with the established jurisprudence of the Boards of Appeal of the EPO (Case Law of the Boards of Appeal, 8th Edition, July 2016, II.C, introduction and

II.C.4.4, in particular decision T 435/91, OJ EPO 1995, 188, Reasons 2.2.1), sufficiency of disclosure can be acknowledged for the subject matter of operative claims 1, 2 and 3 if a skilled person, on the basis of the information provided in the patent specification and, if necessary, using common general knowledge, is able without undue burden, i.e. with reasonable effort, to prepare polyvinylpyrrolidone powder compositions according to claims 1, 2 and 3. In the present case, the objection of lack of sufficiency of disclosure related to the measurement of parameters defining the polyvinylpyrrolidone powder compositions in claims 1, 2 and 3 of the first auxiliary request, namely the K value, the K value lowering ratio and the content of insoluble substances of the polyvinylpyrrolidone powder compositions. In that respect, it is emphasized that the claims of the first auxiliary request are not directed to a specific method of measurement defined by its accuracy and reproducibility, but to polyvinylpyrrolidone powder compositions fulfilling specific parametric requirements.

3.2 While it was not disputed that the parameters defined in claims 1, 2 and 3 were generally known to the skilled person and that they were also defined in the patent in suit (K value in paragraph 23, K value lowering ratio in paragraphs 18-21 and 97 and content of insoluble substances in paragraphs 92-96), the respondent held that the patent in suit did not disclose all the necessary conditions to perform reproducible measurements of these parameters. In particular, it was held that while a measurement of these parameters on polyvinylpyrrolidone powder compositions produced by the method(s) described in the patent in suit could be carried out, the lack of reproducibility of the measurements was such that a

person skilled in the art was not in a position to conclude whether the composition he had obtained was according to the claims of the first auxiliary request or not.

3.3 The arguments of the respondent were based on measurements of the K value, the K value lowering ratio and the content of insoluble substances reported in the letter of the respondent dated 26 August 2015 as well as in Annex I and Annex II provided with the rejoinder to the statement setting out the grounds of appeal and performed on polyvinylpyrrolidone powder compositions prepared according to the methods disclosed in the examples of the patent in suit (protocols provided in the report "PR 00311/1", the report from Dr. Weyandt and the laboratory journals showing the protocols followed for the rework of examples 1 and 2 and comparative example 1 of the patent in suit).

3.4 Regarding the K value and the K value lowering ratio, the experimental data from 26 August 2015 (Table 3) and that reported in Annex I (Tables 4-6) provided by the respondent show that the measurement of these two parameters using the method described in the patent in suit on reworked compositions according to examples 1, 2, 4 and 5 yielded values that differed from those disclosed in the patent in suit (Table 1) and that the K value lowering ratio obtained for all compositions was outside the claimed range of lower than 12%. That, in the opinion of the respondent, established that the methods of measurement of the K value and the K value lowering ratio described in the patent in suit were not accurate nor reproducible.

3.5 It was not argued that polyvinylpyrrolidone powder compositions in accordance with any of claims 1, 2 and

3 could not be obtained by applying the measures defined in the patent in suit, i.e. the methods (1) to (4) as taught in paragraphs 35 to 89 of the specification including the specific measures required in any of claims 1 to 3. The arguments of the respondent concern in fact the repetition of the examples of the patent in suit, i.e. the preparation of polyvinylpyrrolidone powder compositions having specific K values, K value lowering ratios and content of insoluble substances.

3.6 However, the difficulty to provide an exact repetition of the examples of the patent in suit is in the present case not decisive for concluding a lack of sufficiency of disclosure of the claimed invention and can be left unanswered. Firstly, it is the sufficiency of disclosure of the combination of technical features of the invention, i.e. as defined by the terms of the claims (see Rule 43(1) EPC), which has to be assessed and not that of the specific exemplified embodiments, which are not in the present case the subject-matter of a claim. This means that adjusting the various synthesis and measuring conditions to arrive at a product whose parametric values are within the broader ranges of values defined in operative claims 1, 2 or 3 is a far less demanding task for the skilled person. Secondly, according to Rule 42(1)(e) EPC the description shall describe in detail at least one way of carrying out the invention claimed, using examples where appropriate, meaning that the presence of examples is not a mandatory requirement for meeting the requirement of sufficiency of disclosure. What counts is the information provided by the whole patent, including that provided by the examples, if any.

3.7 In the present case, the experimental data relied upon by the respondent, in particular the rework of the composition according to example 2 of the patent in suit in Annex I for which the K value is between 55 and 120 (Table 6: average of 81.33) and the K value lowering ratio is below 12 % (Table 6: 8.41) in accordance with claims 1, 2 and 3 of the first auxiliary request, actually indicates that a skilled person is able to provide a polyvinylpyrrolidone powder composition as defined in said claims, which includes measuring both K value and K value lowering ratio.

3.8 As to the content of insoluble substances, the argument of the respondent was that the measurements of that parameter on compositions obtained by reworking examples 1, 2, 4, 5 according to the patent in suit, as they are reported in the experimental data from 26 August 2015 (Tables 1 and 2) and that reported in Annex I (Tables 1 and 3), differed significantly from the values disclosed in the patent in suit. The argument of the respondent was that the experimental evidence reported in Annex II established that these differences resulted from the use of conditions applied in the course of the filtration and that were not provided in the patent in suit, namely the filtration system chosen in the method, the frit, the pressure applied to the filter and the amount of the solution to filter. However, the observation that the content of insoluble substances defining the claimed compositions is subject to variations depending on the measuring conditions applied in the course of the filtration does not necessarily establishes a lack of sufficient disclosure, once the claims do not contain any restriction concerning those conditions and are therefore open to any conditions which can be said to

be standard in the art.

3.9 In fact, the conditions mentioned by the respondent, the filtration system, the frit, the pressure applied to the filter and the amount of the solution to filter, are all usual in the field of filtration and have a direct influence on the performance of the filtration. Since the content of insoluble substances, as defined in the patent in suit (paragraph 14), is the ratio of dry mass of insoluble substances remaining on a membrane filter after filtration of an aqueous solution of a polyvinylpyrrolidone powder composition and the mass of the composition used to prepare the solution, there can be no doubt that the skilled person would have expected that its value, which is determined by a filtration operation, depends on conditions that are critical to the filtration. The skilled person would have thus naturally considered the selection and the influence of these conditions during the set up of the filtration.

3.10 The next question is whether the selection of an appropriate set of conditions to be applied during the determination of the content of insoluble substances, which is not addressed in the patent in suit, would have been an undue burden for the skilled person. In that respect, Annex II does not establish the presence of an undue burden. On the contrary, the data reported in Annex II shows that it was possible for the respondent to determine, with a reasonable amount of effort, which conditions could be selected to obtain a content of insoluble substances according to the claims of the first auxiliary request (below 70 ppm). In that respect, Annex II shows, apart for the filtration systems which are not described in detail, that without varying the conditions beyond what is common in the

art, values of the content of insoluble substances according to the claims of the first auxiliary request can be obtained. In particular, it is apparent that the polyvinylpyrrolidone powder composition corresponding to the composition of example 1 of the patent in suit that was tested by the respondent has a content of insoluble substances below 70 ppm when selecting the filtration system 3 operated at a pressure of 50 mbar as shown in Table 1 (content of insoluble substances determined to be 62 ppm in that case) or alternatively when a Büchner funnel, allowing a flow of 227 ml/min as shown in Table 4, is used (content of insoluble substances determined to be 9 ppm in that case). It can therefore not be concluded from Annex II that the skilled person would not have been in the position to perform a measurement of the content of insoluble substances as described in the patent in suit.

3.11 The Board concludes from the above that on the basis of the arguments submitted by the respondent, there is no reason to conclude that the subject matter of claims 1, 2 and 3 of the first auxiliary request is not sufficiently disclosed.

4. Remittal

4.1 With regard to the request of remittal made by the parties (section 4 of the letter of 22 March 2019 of the appellant and section IV of the rejoinder to the statement setting out the grounds of appeal of the respondent), it is apparent that the grounds of opposition raised against the patent in suit under Article 100(a) EPC (lack of novelty and inventive step) were not dealt with before the opposition division. In view of that, the Board finds it appropriate to remit the case to the department of first instance for

further prosecution (Article 111(1) EPC).

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:

B. ter Heijden F. Rousseau

Decision electronically authenticated