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Datasheet for the decision of 23 October 2023

Case Number: T 0596/20 - 3.3.04

Application Number: 13709190.6

Publication Number: 2825555

IPC: C07K14/75

Language of the proceedings: EN

Title of invention:
IMPROVED PROCESS FOR PRODUCTION OF FIBRINOGEN AND FIBRINOGEN PRODUCED THEREBY

Patent Proprietor:
Octapharma AG

Opponents:
Strawman Limited
Biotest AG

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Inventive step - (no)
Amendments - extension beyond the content of the application as filed (yes)
Auxiliary requests 5 to 10 - not admitted

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0596/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 23 October 2023

Respondent: (Patent Proprietor)	Octapharma AG Seidenstrasse 2 8853 Lachen (CH)
Representative:	Ullrich & Naumann PartG mbB Schneidmühlstrasse 21 69115 Heidelberg (DE)
Appellant: (Opponent 1)	Strawman Limited Orchard Lea, Horns Lane, Combe, Whitney, Oxfordshire OX29 8NH (GB)
Representative:	Murgitroyd & Company Murgitroyd House 165-169 Scotland Street Glasgow G5 8PL (GB)
Appellant: (Opponent 2)	Biotest AG Landsteinerstraße 3-5 63303 Dreieich (DE)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 14 January 2020 concerning maintenance of the European Patent No. 2825555 in amended form.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 2 825 555 (patent in suit) was granted with a set of 25 claims.

II. The patent in suit was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

III. In the course of the opposition proceedings, the patent proprietor submitted claims of an amended main request and four auxiliary requests (all filed with the patent proprietor's submission of 6 September 2019).

IV. Claim 1 of the ***main request*** reads as follows:

"1. A process for purifying fibrinogen from a fibrinogen containing source by precipitation of fibrinogen by a precipitating agent from a fibrinogen containing solution in the presence of one or more chelating agent(s) and removal of the supernatant from the fibrinogen paste, characterised in that

fibrinogen is extracted from the paste forming a liquid fraction containing fibrinogen and an undissolved residue, which is separated from the liquid, while addition of one or more protease inhibitor(s) is omitted, and

wherein the one or more chelating agent(s) is a Ca^{2+}-chelating agent selected from the group consisting of 1,2-bis(o-amino)ethane-N,N,N',N'-tetraacetic acid (BAPTA), diethylene-triamine-pentaacetic acid (DTPA),

ethylenediamine-tetraacetic acid (EDTA), ethylene-glycol-tetraacetic acid (EGTA) and nitrilo-triacetic acid (NTA)."

V. At the start of the oral proceedings before the opposition division, the patent proprietor stated that it was "in a position to submit further Auxiliary Requests 5-9 if deemed necessary" (see the minutes of the oral proceedings, page 1, paragraph 1), but did not then submit these requests.

VI. The documents cited in the proceedings before the opposition division included the following:

D1: US 6,037,457 A

VII. The decision under appeal is the opposition division's interlocutory decision, announced on 7 November 2019 and posted on 14 January 2020, finding that the patent as amended in the form of the main request met the requirements of the EPC. Inventive step was assessed starting from, *inter alia*, the technical teaching of prior-art document D1.

VIII. Both opponents (appellants) appealed against this decision.

IX. The time limit for replying to the opponents' appeals was four months from notification (see the board's communication of 8 June 2020).

X. The patent proprietor's (respondent's) reply to the opponents' appeals is dated 17 November 2020.

With this reply, the respondent re-filed the claims of the main request that had been held allowable by the opposition division. It also filed sets of claims for nine auxiliary claim requests and documents D51 to D54.

The claims of auxiliary requests 1 to 4 are identical to those of the corresponding claim requests filed with the submission of 6 September 2019 (see point III. above).

Claim 1 of ***auxiliary request 1*** has the same wording as claim 1 of ***auxiliary request 6.*** This claim is identical to claim 1 of the main request (see point IV. above), except that it additionally specifies that:

> *"the one or more chelating agent(s) is added to the fibrinogen containing solution prior to precipitation and all buffers downstream of the precipitation are free of the chelating agent".*

Claim 1 of ***auxiliary request 2*** has the same wording as claim 1 of ***auxiliary request 7***. This claim is identical to claim 1 of the main request, except that it additionally specifies that:

> *"the one or more chelating agent(s) is added to the fibrinogen containing solution prior to precipitation, wherein the addition of the one or more chelating agent(s) is a one-time addition, and all buffers downstream of the precipitation are free of the chelating agent".*

Claim 1 of ***auxiliary request 3*** has the same wording as claim 1 of ***auxiliary request 8***. This claim is identical to claim 1 of the main request, except that it additionally specifies that:

> *"the one or more chelating agent(s) is added to the fibrinogen containing solution prior to a single precipitation, wherein the precipitating agent is glycine and the concentration of the chelating agent is in a range of 3 mM to 100 mM, and wherein the addition of the one or more chelating agent(s) is a one-time addition and all buffers downstream*

of the precipitation are free of the chelating agent".

Claim 1 of ***auxiliary request 4*** has the same wording as claim 1 of ***auxiliary request 9***. This claim is identical to claim 1 of auxiliary requests 3 and 8, except that it additionally specifies that fibrinogen is extracted from the paste

"*for 10 to 120 minutes*".

Claim 1 of ***auxiliary request 5*** is identical to claim 1 of the main request.

XI. In a communication under Article 15(1) RPBA issued in preparation for oral proceedings, the board recalled that it was not in dispute that the respondent had submitted its reply to the appellants' grounds of appeal only after the expiry of the pertinent time limit according to Article 12(1)(c) RPBA set with the board's communication of 8 June 2020. The standard of Article 13(1) RPBA applied with regard to the discretionary admittance of any part of this submission, including the auxiliary requests.

XII. Oral proceedings before the board took place on 23 October 2023. In the course of the oral proceedings, the patent proprietor presented another set of claims as auxiliary request 10.

XIII. Claim 1 of **auxiliary request 10** is identical to claim 1 of the main request, except that it additionally specifies:

"and wherein the fibrinogen containing source is cryoprecipitate".

XIV. The appellants' arguments may be summarised as follows:

Inventive step (main request)

Claim 1 of the main request did not involve an inventive step starting from the disclosure in D1 (in particular, example 4 of that document).

The only technical feature distinguishing the process of claim 1 from the process of D1 was the required absence of protease inhibitors, unless these were also chelating agents defined in claim 1, as in the case of EDTA and EGTA. The objective technical problem was to provide an alternative purification process.

The teaching of D1, in particular in column 8 of that document, encompassed the process as defined in claim 1 of the main request where it involved the use of EDTA and/or EGTA in the absence of other protease inhibitors. Even if such embodiments were to be considered as less preferred within D1, the arbitrary selection of a less preferred embodiment still could not establish an inventive step.

Admittance of auxiliary requests 1 to 9

The respondent had not filed the auxiliary requests within the time limit set for replying to the grounds of appeal. In the interest of procedural economy, they should not be admitted.

Remittal

No need could be seen for remitting the case to the opposition division.

Amendments (auxiliary requests 1 to 4)

The technical features added in claim 1 of auxiliary request 1 were disclosed in the application as filed only in combination with further features which, however, were absent in claim 1 of auxiliary request 1.

The amendments constituted an impermissible generalisation. The additional amendments in claim 1 of each of auxiliary requests 2 to 4 did not overcome this objection.

Admittance of auxiliary request 10

Auxiliary request 10 was an attempt to respond, at a very late stage of the proceedings, to a long-known issue that the appellants had raised and pursued both in the proceedings before the opposition division and in the appeal proceedings. This request's late submission on the day of the oral proceedings before the board was not justified. If admitted, it would moreover change the focus of the debate as it removed the amendments made in the higher-ranking auxiliary requests and introduced a limitation taken from the description.

XV. The respondent's arguments may be summarised as follows:

Inventive step (main request)

D1 was a possible starting point for the assessment of inventive step. However, as it related to the production and harvesting of recombinant fibrinogen from protein production cell cultures rather than from blood or blood plasma, it did not represent the closest prior art.

The process according to claim 1 differed from that described in D1 not only in the nature of the proteases present, but also in the process step of "extracting" fibrinogen from the paste forming a liquid fraction containing fibrinogen and an undissolved residue. The principle behind this was that the extraction was to be deliberately stopped at a certain point, in order to obtain an optimised balance between purity and

yield. Because impurities with a high molecular weight were purposefully and selectively left behind in the undissolved material, the resulting fibrinogen concentrate was purer in its quality.

This selective extraction step and the associated advantage of improved purity were not taught in D1. If example 4 of D1 mentioned undissolved material, this was presumably never-dissolvable material, which could not be equated to the undissolved residue in claim 1 of the main request.

Furthermore, D1, for instance in example 4, required a cocktail of different types of protease inhibitors to be present. A person skilled in the art would not have found it obvious to restrict the process to the exclusive use of EDTA and/or EGTA, which belonged to the same class of inhibitors as both were inhibitors of metalloproteases.

Admittance of auxiliary requests 1 to 9

Unusual circumstances had caused the delay in filing the reply to the appeals. In a period characterised by disrupted workflows due to the COVID-19 pandemic, the initial inadvertent miscalculation of the internal response deadline had remained unnoticed. The delay of one month was short and inadvertent, it did not provide the respondent with any strategic advantage, and auxiliary requests 1 to 9 were not new and did not add to the complexity of the case.

Remittal

The fact that the board's interpretation of claim 1 differed from that chosen by the opposition division meant that the opposition division's decision had been based on a fundamentally flawed interpretation of the decisive distinguishing feature. The case should

therefore be remitted to the opposition division on the basis of the claims of the auxiliary requests, to provide the respondent with the opportunity of obtaining an assessment of the case at two instances.

Amendments (auxiliary requests 1 to 4)

The amendments in claim 1 of auxiliary request 1 were based on page 5, lines 16 to 19 and page 15, lines 7 to 9 of the description as filed.

The feature relating to "one-time addition" of the chelating agent addressed the objection of added subject-matter that had been raised against claim 1 of auxiliary request 1.

The amendments in auxiliary request 2 were based, additionally, on page 5, lines 24 to 31, page 6, lines 10 to 18 and page 14, table 1. As could be inferred from the information presented in table 1, the concentration range of 3 mM to 10 mM recited on page 5, lines 6 to 8, was not a necessary feature.

The further limitations in auxiliary request 3, which specified a particular precipitating agent and a particular concentration range of the chelating agent, were supported throughout the application as filed, for example by the disclosure on page 10, line 21.

The extraction time indicated in auxiliary request 4 was supported throughout the application as filed and was based, for example, on the paragraph spanning pages 14 and 15 of the description as filed.

Admittance of auxiliary request 10

Auxiliary request 10 could not have been filed at an earlier time as it was presented in response to an issue which had been raised for the first time, in the

context of claim interpretation, in point 2.1 of the board's communication under Article 15(1) RPBA.

XVI. Appellant 1 (opponent 1) requested that the decision under appeal be set aside and that the patent be revoked. Appellant 1 also requested that documents D51 to D54 and auxiliary requests 5 to 10 not be admitted.

XVII. Appellant 2 (opponent 2) requested that the decision under appeal be set aside and that the patent be revoked. Appellant 2 furthermore requested that the respondent's reply to the appeals and any documents and observations filed therewith, in particular also auxiliary requests 1 to 9, not be admitted, and that, furthermore, auxiliary request 10 not be admitted.

XVIII. The respondent (patent proprietor) requested that the appeals be dismissed and that the patent be maintained in the version of the main request deemed allowable by the opposition division

or, in the alternative, that the case be remitted to the opposition division for further prosecution based on the claims of auxiliary requests 1 to 9, all filed with the respondent's reply of 17 November 2020 to the appeals

or, in the further alternative, that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 1 to 10 (auxiliary request 10 having been filed on 23 October 2023).

The respondent furthermore requested that its entire submission of 17 November 2020 be admitted under Article 13(1) RPBA.

Reasons for the Decision

1. Inventive step (Articles 100(a), 52 (1) and 56 EPC) - main request

Patent in suit

1.1 The patent in suit seeks to provide a process for purifying fibrinogen (see paragraph [0001]).

1.2 This task is to be accomplished by the process defined in claim 1 of the main request (see point IV. above).

Starting point in the prior art

1.3 If inventive step is to be acknowledged, the claimed subject-matter must be inventive starting from any potential starting point in the prior art. Since the appellants raised an objection of lack of inventive step starting from the disclosure of document D1, this approach was considered by the board.

1.4 Document D1 relates to a method of producing and purifying recombinant fibrinogen. The purification involves, *inter alia*, concentrating the fibrinogen in the presence of at least one protease inhibitor to prevent degradation of the fibrinogen by proteases (see D1, claim 1). This at least one protease inhibitor may be, *inter alia*, EDTA or EGTA (claim 8 and column 8, lines 18 to 33). The concentration step may be carried out by precipitation with ammonium sulphate (claim 11, column 7, line 64 to column 8, line 17). Affinity chromatography or anion exchange chromatography follows as a further purification step (claim 1 and column 2, lines 53 to 67).

1.5 According to example 4 of D1 (see column 10 in D1), fibrinogen was precipitated from a liquid medium by addition of 40% saturated ammonium sulphate, in the presence of several protease inhibitors (ε-ACA, EDTA, aprotinin, pepstatin, leupeptin, PMSF and benzamidine). The precipitate was collected by centrifugation. The liquid obtained after treating the fibrinogen pellets with a solvent buffer medium for several hours was centrifuged "to remove undissolved material" (column 10, lines 45 to 47).

Technical problem and solution

1.6 The type of the fibrinogen-containing source, the expression "is extracted" used in claim 1 and the formation of "undissolved residue" are not features that can distinguish the claimed subject-matter from the disclosure in D1, for the following reasons:

1.6.1 Claim 1 does not further define or restrict the fibrinogen-containing source. This is consistent with the statement in paragraph [0045] of the patent in suit that all fibrinogen-containing sources can be used. Thus, the process of D1 does not differ from the process of the patent in suit in the fibrinogen-containing source.

1.6.2 According to the respondent, the expression "is extracted" employed in claim 1 is presumed to imply a specific concept for this process step, which involves the contact with the solvent medium being stopped at a specific point in time and in a purposeful manner, even if some of the fibrinogen is not yet dissolved, in order to obtain an optimised balance between purity and yield.

1.6.3 This argument cannot succeed, since there is no indication in claim 1 of such a concept. The mere use of the expression "is extracted" does not imply any particular measure except that of transferring the fibrinogen from the precipitate into a liquid medium. No criteria are mentioned, either, for establishing an optimised balance between purity and yield.

1.6.4 The occurrence of an undissolved residue recited in claim 1 of the main request is a limiting feature expressed in terms of a result to be achieved. Nothing permits the conclusion to be drawn that undissolved residue will inevitably occur when the preceding process steps as set out in claim 1 are performed. Rather, this will depend on the composition of the starting material (the "fibrinogen containing solution" and the "fibrinogen containing source") in combination with the specific further materials and conditions used in a given embodiment of the claimed process. Claim 1 leaves these materials and conditions largely undefined. The residue itself is not characterised.

1.6.5 In these circumstances, the "undissolved material" mentioned in example 4 of D1 (see point 1.5 above) has to be considered a disclosure of "undissolved residue" within the unspecific meaning of claim 1.

1.7 The sole feature distinguishing the process of claim 1 from the purification process described in example 4 of D1 is the requirement that "addition of one or more protease inhibitor(s) is omitted". In the context and terminology of the patent in suit, this means protease inhibitors other than those listed as chelating agents in claim 1.

1.8 It has not been shown on the basis of comparative tests whether the quality and properties of a product

obtained according to example 4 of D1 would differ from that of a product obtained by a process according to claim 1, using no protease inhibitors except for EDTA and/or EGTA. Since no pertinent comparative data is on file, the objective technical problem can only be to provide a further process for purifying fibrinogen.

1.9 This technical problem is solved by the process of claim 1.

Obviousness of the solution

1.10 D1 mentions that the fibrinogen is produced in serum-free conditions, because proteases found therein will degrade the fibrinogen (column 5, lines 48 to 50; example 4, column 10, line 12). Nevertheless, carrying out the concentration and purification steps in the presence of one or more protease inhibitor(s) is a preferred embodiment in D1 (see column 8, second paragraph). According to the process claims in D1, at least one protease inhibitor must be present.

1.11 In this context, D1 identifies EDTA and EGTA (both chelating agents according to claim 1 of the present main request) as eligible protease inhibitors. EDTA was used, among other compounds, as a protease inhibitor in the process described in example 4 of D1.

1.12 Thus, the skilled person would still be working within the scope of preferred embodiments taught in D1 if they omitted the use of protease inhibitor(s) other than EDTA and/or EGTA, in conformity with present claim 1, to provide an alternative purification process to that described in example 4 of D1.

1.13 The respondent contended that the person skilled in the art would not have considered using only EDTA and/or EGTA. Both were known to be metalloprotease inhibitors,

and the skilled person's expectation would have been that metalloprotease inhibitors alone would not perform as well as a mixture of different classes of protease inhibitors (as used in example 4 of D1).

1.14 This argument cannot succeed for the following reasons:

1.14.1 While the presence of a "cocktail" of two or more protease inhibitors is presented as an even more preferred option (see D1: column 8, lines 18 to 33), there is nevertheless no teaching in D1 that a larger number of protease inhibitors (three or more) or a particular combination of different classes of protease inhibitors is necessary or essential.

1.14.2 The respondent did not show that the person skilled in the art would have been deterred by a clear expectation of failure. It was not shown that the teaching in D1 itself (namely, that any one or two protease inhibitors among those listed in D1 may be used) would have been trumped by a contrary expectation of the skilled person, based on common general knowledge, that the fibrinogen would inevitably be degraded in the absence of a larger variety of protease inhibitors.

1.15 In conclusion, the skilled person seeking to solve the objective technical problem would have found it obvious to consider a process as defined in claim 1 of the main request, because this process variation is taught in D1 itself.

1.16 For these reasons, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

2. Admittance of auxiliary requests 1 to 4 (Article 13(1) RPBA)

Auxiliary requests 1 to 4 were admitted under Article 13(1) RPBA. Since these requests were ultimately held unallowable (see section 4. below), a reasoned decision regarding their admittance is not required.

3. Remittal (Article 111(1) EPC)

3.1 Contrary to the respondent's view, the fact that the board's conclusions regarding the allowability of the main request differed from those of the opposition division does not mean that the proceedings before the opposition division suffered from a fundamental deficiency.

3.2 Also, the amendments made in the auxiliary requests do not have the effect of raising fundamentally different issues in comparison with the main request.

3.3 As the respondent did not provide other specific reasons in favour of remittal, the board decided not to remit the case to the opposition division.

4. Amendments (Article 123(2) EPC) - auxiliary requests 1 to 4

Auxiliary request 1

4.1 In comparison with claim 1 of the main request, claim 1 of auxiliary request 1 additionally specifies that:

> *"the one or more chelating agent(s) is added to the fibrinogen containing solution prior to precipitation and all buffers downstream of the precipitation are free of the chelating agent".*

4.2 The feature stating that the one or more chelating agent(s) is added to the fibrinogen containing solution prior to precipitation is redundant as this is already evident from the preceding passage in claim 1, which states that the fibrinogen is precipitated from a fibrinogen containing solution in the presence of one or more chelating agent(s).

4.3 To support the feature requiring that all buffers downstream of the precipitation be free of the one or more chelating agent(s), the respondent relied on the passage on page 5, lines 16 to 19 in the application as filed, which reads:

> *"Consequently, all buffers used downstream of the precipitation, e.g. equilibration-, washing- and elution buffers used for chromatography or the buffer used during concentration by ultra-/ diafiltration, should be free of Ca^{2+} chelating agents, which are defined below."*

4.4 However, the cited passage reads on from the preceding paragraph (page 5, lines 6 to 15), which relates to a particular embodiment that is described as follows:

> *"It was further surprisingly observed that a one-time addition of a rather small amount of at least one chelating agent prior to precipitation, resulting in a total chelating agent concentration of about 3-10 mM, is sufficient for the present invention to provide both excellent yield and filterability [...]."* (page 5, lines 6 to 9)

The text goes on to explain that residual amounts of chelating agent can be removed downstream and a product free of chelating agents is preferable (page 5, lines 10 to 15). This reads on to page 5, lines 16 to 19 (see point 4.3 above).

4.5 Thus, the new feature in claim 1 of auxiliary request 1 was only disclosed in the application as filed in the context of a particular process embodiment which requires the total chelating agent concentration, upon one-time addition of the chelating agent, to be 3-10 mM.

4.6 Since the combination of features according to claim 1 of auxiliary request 1 does not include these further limiting features, it is not directly and unambiguously disclosed in the application as filed, contrary to the requirements of Article 123(2) EPC.

Auxiliary request 2

4.7 In comparison with claim 1 of the main request, claim 1 of auxiliary request 2 additionally specifies that:

> *"the one or more chelating agent(s) is added to the fibrinogen containing solution prior to precipitation, wherein the addition of the one or more chelating agent(s) is a one-time addition, and all buffers downstream of the precipitation are free of the chelating agent".*

4.8 In support of the added features in claim 1 of auxiliary request 2, and apart from the passage on page 5, lines 16 to 19, the respondent mentioned page 5, lines 24 to 31, page 6, lines 10 to 18 and table 1 on page 14. The respondent argued that it could be inferred from the information presented in table 1 that the concentration range of 3 mM to 10 mM recited on page 5, lines 6 to 8, was not a necessary feature.

4.9 The passage starting on page 5, line 24, relates to systemic application of a fibrinogen product free of chelating agents rather than to the process for its preparation and cannot provide additional support.

4.10 The passage on page 6 repeats the general process steps and mentions that the aqueous medium for extracting the fibrinogen from the precipitate is "void of the chelating agent", but this passage does not include the requirement that all buffers downstream must be free of the chelating agent.

4.11 Table 1 reports the concentrations of the chelating agents which were used in the examples, and the content of compounds of higher molecular weight than fibrinogen in the product obtained. Varying concentrations were used - in most cases 3, 5 or 10 mmol/l. In further examples, concentrations of 1, 20 or 50 mmol/l were used.

However, it is not apparent why it should be inferred from this unrelated passage that the concentration range of 3-10 mM (i.e. 3-10 mmol/l), disclosed as a feature of the specific process embodiment described on page 5, lines 6 to 19, may be omitted in claim 1. The embodiments of examples V and VI, where higher concentrations were tested, are separate embodiments, which are delimited further by the specific materials and conditions used (as described on page 12, line 30 to page 14, line 2).

The required support for the combination of features defined in claim 1 must be provided by direct and unambiguous disclosure in the application as filed. It would be going too far to deconstruct the specific embodiment disclosed on page 5 by removing the limitation regarding the concentration range simply because the application discloses other embodiments in which different concentrations were used.

4.12 For these reasons, the subject-matter of claim 1 of auxiliary request 2 does not meet the requirements of Article 123(2) EPC.

Auxiliary requests 3 and 4

4.13 At the oral proceedings before the board, the respondent referred to its written submissions in support of the amendments in auxiliary requests 3 and 4.

4.14 Claim 1 in each of these requests contains essentially the same added features as claim 1 of auxiliary request 2.

4.15 The further added features in each request do not address or overcome the objections set out above in the context of claim 1 of auxiliary request 1 and claim 1 of auxiliary request 2.

4.16 Claim 1 of auxiliary request 3 requires a single precipitation, wherein the precipitation agent is glycine and the concentration of the chelating agent is in a range of 3 mM to 100 mM. Claim 1 of auxiliary request 4 contains the same added features and additionally specifies that fibrinogen is extracted from the paste for 10 to 120 minutes.

4.17 The text passages indicated in the respondent's written submissions do not provide the required direct and unambiguous support in the application as filed for either of these claims.

4.18 Page 10, line 21 was mentioned in the context of auxiliary request 3. Lines 21 to 22 contain the sentence *"Already a single precipitation e.g. with glycine provides a fibrinogen paste sufficiently pure for further processing"*. However, this passage is not a general disclosure but is presented in the context of a specific embodiment which uses cryoprecipitate as the starting material and defines a large number of process conditions (page 9, line 17 to page 10,

line 21). Thus, the cited passage does not provide direct and unambiguous disclosure of the combination of features as defined in claim 1 of auxiliary request 3.

4.19 The respondent also indicated that the extraction time indicated in auxiliary request 4 was supported by the paragraph spanning pages 14 and 15 of the description as filed.

4.20 This passage relates to the suitable extraction time range that was determined in the context of the specific examples described in the application. In these experiments, specified conditions and materials were used. This does not amount to general disclosure and neither does it provide support for combination with the other technical features of claim 1 in auxiliary request 4.

4.21 The respondent also submitted that the added features in auxiliary requests 3 and 4 found support "throughout the description". This argument is too unspecific to be taken into account.

4.22 For these reasons, the subject-matter of claim 1 in auxiliary request 3 and of claim 1 in auxiliary request 4 does not meet the requirements of Article 123(2) EPC.

5. Admittance of auxiliary requests 5 to 9 (Article 13(1) RPBA)

5.1 As already mentioned (see point X. above), claim 1 of auxiliary request 5 is identical to claim 1 of the main request. Claim 1 in auxiliary request 6 is identical to claim 1 of auxiliary request 1, and claims 1 in auxiliary requests 7 to 9 are identical

to the corresponding claims 1 in auxiliary requests 2 to 4.

5.2 Since, under these circumstances, it was *prima facie* evident that auxiliary requests 5 to 9 could not overcome the objections set out above against the main request and auxiliary requests 1 to 4, the board decided not to admit auxiliary requests 5 to 9.

6. Admittance of auxiliary request 10 (Article 13(2) RPBA)

6.1 The respondent submitted auxiliary request 10 for the first time in the afternoon of the day of the oral proceedings before the board. The filing of a new claim request is an amendment to the respondent's case. In view of the timing of this request, the provisions of Article 13(2) RPBA apply.

6.2 The respondent contended that the filing of auxiliary request 10 had been prompted by exceptional circumstances. This request had been filed in response to the board's communication under Article 15(1) RPBA that provided, in point 2.1, an interpretation of the feature "forming [...] an undissolved residue", this being the first time such an interpretation had been presented in the context of claim interpretation.

6.3 The board's observation in the communication in question is the following (see also point 1.6.4 above):

> *"The board considers that the occurrence of an undissolved residue as per line 6 of claim 1 is a limiting feature and a result to be achieved. Nothing permits the conclusion to be drawn that undissolved residue will inevitably occur when the preceding process steps as set out in claim 1 are performed. Rather, this will depend on the composition of the starting material (the*

"fibrinogen containing solution" and the "fibrinogen containing source") in combination with the specific further materials/agents and conditions used in a given process embodiment. Claim 1 leaves these materials and conditions largely undefined. The residue itself is not characterised."

6.4 The respondent's claim to exceptional circumstances cannot succeed, because the board's comment relates to an aspect that had always been central to the case and takes up a view that had been expressed by appellant 2 in its statement setting out the grounds of appeal. This is evident from appellant 2's statement of grounds, first two full paragraphs on page 23, which read as follows:

"Although the proprietor clearly and repeatedly confirmed during the first instance (with submission dated September 20, 2018) that a solid residue is inevitably achieved by precipitating fibrinogen from solution in the presence of a chelating agent forming a fibrinogen paste and extracting the paste, the Opposition Division in the appealed decision argued that such a solid residue would not be inevitably formed in the prior art processes, coming to the (incorrect) conclusion that the Main Request was novel and inventive.

The opponents, during the oral proceedings, emphasized that in this case the skilled person cannot know under which conditions an undissolved residue can reliably be achieved to reproduce the process according to claim 1. Instead, a variety of factors and process conditions can impact the formation of the undissolved residue, such as the starting material, buffer system, buffer concentration, extraction time, temperature etc.,

resulting in an undue burden for the skilled person to find out the necessary requirements to achieve an undissolved residue as claimed and to perform the claimed process."

6.5 Thus, the respondent's argument must fail. Parties should be prepared for the eventuality that a board might agree with an opposing party's argument. This is not an exceptional circumstance. In the present context, it is not relevant that the board's observation was formally presented under the heading "claim interpretation", while the appellant's remarks were presented in the context of arguments relating to sufficiency of disclosure. The content is the same in both cases.

6.6 For these reasons, the board decided not to admit auxiliary request 10 under Article 13(2) RPBA.

7. Admittance of new evidence

7.1 The respondent filed documents D51 to D54 in support of its arguments in relation to novelty over document D13 (US 7,009,039 B2), i.e. a document different from D1 (see pages 15, 16 and 18 of the submission of 17 November 2020). A decision on the admittance of D51 to D54 was not required since the respondent did not rely on these documents in the context of the issues of inventive step and added matter that were relevant to the board's reasoning set out above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated